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Impulse Assessment of the Moldex[®] Pura-Fit[®] Uncorded Earplug

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Executive Summary

The impulse peak insertion loss (IPIL) is the standard measure of attenuation provided by hearing protection devices (HPDs) in response to an impulsive noise. This technical memorandum describes the IPIL testing conducted and the calculated mean IPIL values for the Moldex® Pura-Fit® Uncorded Earplug (Pura-Fit® Uncorded; Model: 6800). Testing was in accordance with the American National Standards Institute (ANSI) standard S12.42-2010, Methods for the Measurement of Insertion Loss of Hearing Protection Devices in Continuous or Impulsive Noise Using Microphone-in-Real-Ear or Acoustic Test Fixture Procedures. All samples were tested at the nominal levels of 160 and 170 decibel peak (dBp, re: 20 µPa). A total of five samples were fitted to an acoustic test fixture two times each for a total of 10 trials per test level. No samples of the HPD were rejected. The mean and standard deviation (SD) IPIL values were 54.4 (2.7) dB SPL at 160 dBp and 54.6 (2.2) dB SPL at 170 dBp (see Table 1). These results suggest that when properly fit and functional, the Pura-Fit® Uncorded will adequately protect (i.e., reduce exposure to less than 140 dBp) against impulses below 180.0 dBp.

Table 1.

Pura-Fit® Uncorded mean (SD) IPIL value (in dB) for all test conditions.

160 dBp	170 dBp
54.4 (2.7)	54.6 (2.2)

Introduction

The Moldex® Pura-Fit® Uncorded Earplug (Pura-Fit® Uncorded; Moldex-Metric Inc., Culver City, CA) is a universal sized, single use, uncorded passive plug made of polyvinyl chloride-free (PVC-free) low-pressure foam. According to Moldex-Metric, Inc. (2019), the longer length and tapered design of the Pura-Fit® is intended to allow earplugs to easily be grasped and inserted into all ear canal sizes. The “foam is formulated for softness and comfort, and the outer surface is smooth, so it doesn’t irritate the ear canal” (Moldex-Metric, Inc., 2019, p. 1).

Per the Department of Defense Instruction 6055.12 (2019), the exposure limit for impulse noise is 140 peak decibels (dBP). Therefore, should an impulse noise meet or exceed 140 dBP (e.g., artillery fire, grenade, small arm weapon fire, large caliber weapon fire), hearing conservation efforts must be put into place. One conservation measure used to reduce the user’s noise hazard below the 140 dBP limit is hearing protection devices (HPDs) like that of an earplug or earmuff.

To determine if the issued HPD will reduce the noise exposure below the 140 dBP limit, the impulse peak insertion loss (IPIL) value of the issued and/or used HPD should be subtracted from the impulse noise level (Department of Defense, 2015). The IPIL value is the standard metric (ANSI/ASA S12.42) used to determine the amount of protection afforded by a HPD in response to impulse noise. At present, the IPIL value of the Pura-Fit® Uncorded at 160 and 170 dBP is unknown. The current effort determined the IPIL value for the Moldex® Pura-Fit® Uncorded Earplug. In addition to reporting an overall device IPIL, ear-specific IPILs are reported for the tested nominal levels.

Methods

Facility & Personnel

IPIL testing described herein was completed in the Naval Submarine Medical Research Laboratory (NSMRL) 1000 m³ anechoic chamber in order to minimize any effects of sound reflections.

Equipment

Hardware. Acoustic impulses were generated by NSMRL’s 4 inch (in., 10.2 centimeters (cm)) shock tube (B/C Precision, Inc., Greendale, IN). The shock tube pressure chamber is approximately 34 in. (86.4 cm) long, with an inner diameter of 4 in. (10.2 cm). A 64 in. (162.6 cm) long catenoidal tube horn consisting of four welded steel flat-projection sheets forming a square cross section was connected to the shock tube using a PVC 4.5 in. (11.4 cm) coupler. An industrial air compressor (ILA#1883054; Industrial Air Corporation, Memphis, TN) supplied pressurized air (900 kilopascal) to the shock tube. For each trial, a 7 in. (17.8 cm) by 7 in. (17.8 cm) acetate sheet (Grafix Plastic, Maple Heights, OH) was used as a membrane between the pressurized chamber and the catenoidal tube horn to enable pressurization of the air chamber. Each acetate sheet was 0.002 inches (2.0 mil) thick.

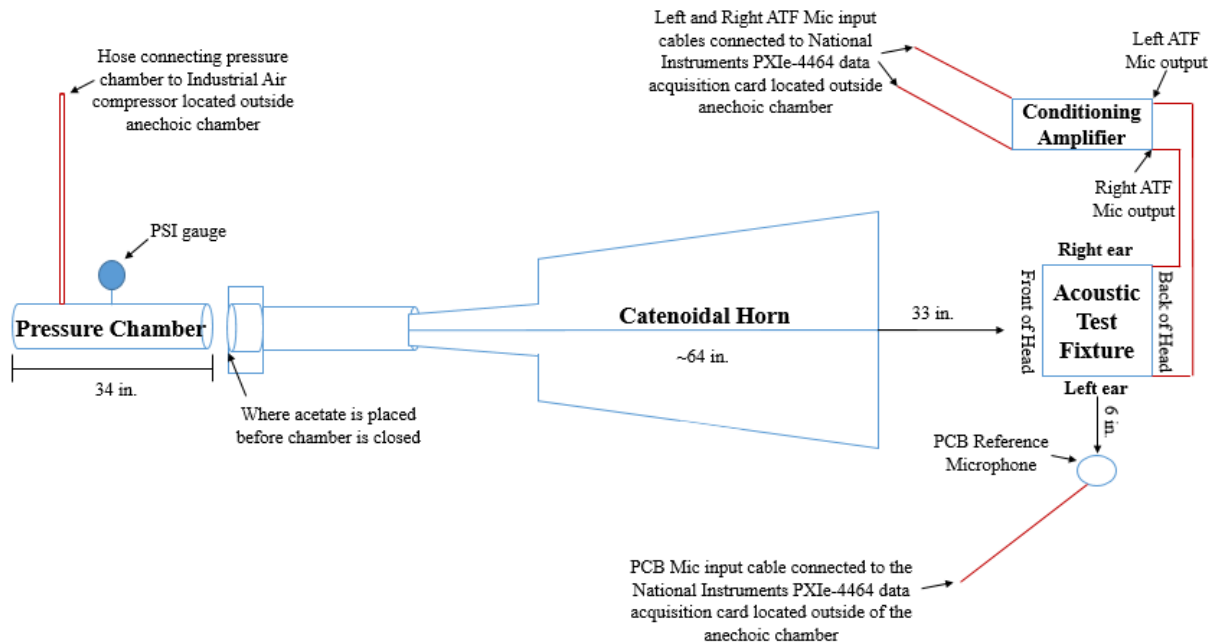
All waveforms were recorded with the ANSI/ASA S12.42 (2010) compliant GRAS 45CB acoustic test fixture (ATF) along with GRAS RA0045-S7 Ear Simulators

(GRAS Sound and Vibration, Twinsburg, OH). The ATF was connected to a conditioning amplifier which served as the power supply (GRAS Type 12AA; GRAS Sound and Vibration, Twinsburg, OH). As required by ANSI/ASA S12.42/2010, the ATF was placed to front-face (i.e., nose facing) the catenoidal tube horn at 0° elevation and 0° azimuth.

A reference microphone (Type 378C20; PCB Piezotronics Inc., Depew, NY) was placed 6 in. (15.2 cm) from the ATF left pinna. The reference microphone, the left ATF microphone, and the right ATF microphone were calibrated each morning prior to data collection at 124 dB sound pressure level (SPL) using a 250 hertz (Hz) tone. A diagram depicting the aerial view of the NSMRL 4 in. (10.2 cm) shock tube and test system can be seen in Figure 1.

Figure 1.

Diagram of the NSMRL Acoustic Shock Tube and ATF.



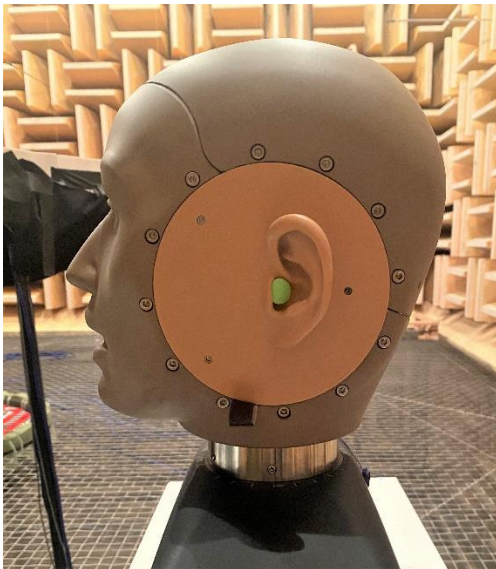
Data Acquisition System. The data acquisition system (NI chassis PXIe-1071 with NI PXIe-4460 and NI PXIe-4464; National Instruments Corp., Austin, TX) was controlled by a standalone laptop computer running project specific software (LabVIEW; National Instruments Corp., Austin, TX). The data acquisition system was connected to the laptop using an MXI cord and host interface card (NI PXIe-8360). The software controlled the acquisition of waveforms from the three source microphones (left ATF microphone, right ATF microphone, and a reference microphone) at a sampling rate of 204.8 k Samples/second during each impulse recording. Pre-trigger settings were 1024 samples per 0.005 seconds, with a trigger level of 110 dB SPL. Each recording was 0.3 seconds in duration.

Rather than using an ANSI/ASA S12.42-2010 standardized in-line analog external Bessel filter (6th order, corner frequency 20.0 kHz [3 dB down]) to filter impulses during data acquisition, anti-alias filtering was accomplished by an analog filter and a digital filter. First, an electronic analog anti-aliasing filter (corner frequency of 93.0 kHz [3 dB down]) was applied to all waveforms by the National Instruments data acquisition system during data collection. This deviation was made due to equipment and software limitations.

The custom-written software program saved all recorded waveforms as files (.tdms), which were exported and converted to data files using an additional custom software programming script. The script compiled the reference PCB microphone, left ATF microphone, and right ATF microphone channels into a file (.mat) that saved variables for input to analysis script (MATLAB) similar to the script provided in Annex H of the ANSI/ASA S12.42-2010 standard. Minor alterations were made to the analysis script in order to accept 160 decibel peak (dBP) and 170 dBP data (see Data Analysis below).

Hearing Protection Device Samples. Five samples of the Moldex[®] Pura-Fit[®] Uncorded Earplugs (Manufacturer Product Number: 6800) were tested IAW ANSI/ASA S12.42-2010. Each sample, consisting of one set of two earplugs, was randomly assigned a number 1 through 5. Each earplug in the sampled set was labeled 'L' for left or 'R' for right to indicate which ATF ear they were to be inserted for all trials.

Figure 2.
Pura-Fit[®] Uncorded Earplugs.



Procedure

Each sampled HPD set was fitted to the ATF twice, resulting in two trials (trials A and B) per sample, and 10 total trials per nominal level test condition (160 and 170 dBP). No samples of the HPD were rejected. To achieve an appropriate fit that would provide maximum attenuation, each sample was expertly fitted to the ATF IAW instructions on the device packaging. The manufacturer fitting guidelines stated that all samples be inspected for any wear, extreme hardness, or damage prior to use. Once inspected, each earplug was rolled down into a thin and wrinkle-free cylinder, inserted into the ear canal, held in place for 30 to 60 seconds until expanded, released and then pushed in again for 5 seconds to ensure proper fit (Moldex-Metric, Inc, 2016). Earplugs were given at least two minutes to fully expand in the ATF ear canal before impulse testing was performed.

Testing at the 130 and 150 dBP nominal levels was omitted, and the nominal level of 160 dBP was incorporated. Because of equipment and material limitations, impulses generated with the NSMRL 4 in. (10.2 cm) shock tube at levels below the nominal level of 160 dBP were found to result in waveforms without a shock front. At the measured levels described herein, all generated impulses had a shock front. Inclusion of the 160 dBP nominal level allowed the range of applicability to be extended down to 150 dBP. Due to non-linear effects on IPIL, it is best to use IPIL values measured close to the level of the predicted exposure (Department of Defense, 2015). Although many weapons systems used in the US Navy produce impulses around 170 dBP, there are several that produce impulses between 150 dBP and 165 dBP. Measuring the IPIL at 160 dBP provides IPIL values which are better estimates of the IPIL at those levels of exposure.

Impulse noises were presented to the ATF in the occluded (i.e., HPD inserted) and unoccluded (i.e., without the HPD inserted) test configurations. For all occluded measures, the earplugs were fitted on the ATF IAW the specifications outlined in ANSI/ASA S12.42-2010. Each HPD sample was exposed to two impulses at each tested nominal level. Adequate pressure for each impulse was determined by increasing pressure (measured in pounds per square inch [psi]) to a point within a pre-specified range necessary for producing either 160 dBP (19.5 to 22.1 psi, 134 to 152 kilopascals (kPa)) or 170 dBP (28.5 to 29.5 psi, 197 to 203 kPa) nominal level using the NSMRL 4 in. (10.2 cm) acoustic shock tube. The acetate was then punctured using a manual trigger, releasing pressurized air into the catenoidal horn, which created an impulse wave through the catenoidal horn to the ATF. The peak decibel level emitted was dependent upon the amount of air pressure released.

In place of the ANSI/ASA S12.42-2010 standardized calibration impulses at 130 and 150 dBP, six calibration impulses were generated at the 160 dBP nominal level in the unoccluded (i.e., without HPD) test configuration. Three of these impulses were generated before, and three were generated after testing at 160 dBP. Calibrations were not completed at the 170 dBP nominal level due to exposure limitations of the ATF right and left microphones.

Data Analysis

MATLAB (Natick, MA) was used to calculate IPIL values at the 160 and 170 dBP nominal levels and to generate all waveform graphs. The mean pressure of each

waveform was subtracted from the waveforms to remove any constant offset. The peak levels were then calculated by converting the maximum absolute value of each waveform into dB SPL. The transfer functions of the free-field probe to each ear of the ATF was calculated for the unoccluded waveforms gathered at the 160 dBP nominal level. The mean transfer function for each ear was then calculated, and the first element of the transfer function was set to zero in order to avoid calculations at 0 Hz. The fit of the mean transfer function was tested by applying the mean transfer function for each ear to the free-field probe data gathered in the 160 dBP nominal level. The difference of the maximum absolute values of the calculated values and the measured values was then calculated, converted to dB SPL, and displayed.

The calculated IPIL value (in dB) equaled the mean difference of the maximum absolute value of the waveforms from the ears of the ATF in dB SPL and the maximum absolute value of the estimated values of the unoccluded ears in dB SPL. The estimated values of the unoccluded ears are the waveforms from the free-field probe with the mean transfer function applied to them. These values were calculated for each ear in each trial and condition. The mean values were calculated across both ears and trials, resulting in a displayed mean for each nominal level (i.e., 160 dBP and 170 dBP). Every waveform was plotted with time on the x-axis and pressure on the y-axis. The transfer functions were not plotted.

Deviating from ANSI/ASA S12.42-2010, a second digital Butterworth filter (6th order, low-pass, corner frequency of 20 kHz [3 dB down]) was applied to all recordings by the MATLAB post-processing script. This digital filter was used to mimic the effect of the ANSI/ASA S12.42-2010 standard required anti-aliasing Bessel filter which was omitted due to equipment limitations.

Results

As shown in Table 2, the overall mean (SD) IPIL value was 54.4 (2.7) dB at the 160 dBP test condition and 54.6 (2.2) dB at the 170 dBP test condition. Calculated IPIL values for all individual sample trials ranged between 50.3 and 60.3 dB at the 160 dBP test condition and between 51.6 and 59.4 dB at the 170 dBP test condition. The waveforms for all trials with the Pura-Fit[®] Uncorded are provided in Appendices A to F.

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Table 2.*Mean (SD) IPIL values (in dB) for Tested Pura-Fit® Uncorded Samples.*

	160 dBP		170 dBP	
	<i>Right</i>	<i>Left</i>	<i>Right</i>	<i>Left</i>
HPD 1, Trial A	54.1	58.3	55.3	59.4
HPD 1, Trial B	52.4	55.3	53.1	56.0
HPD 2, Trial A	56.0	56.6	54.1	53.7
HPD 2, Trial B	54.6	57.4	56.0	59.1
HPD 3, Trial A	51.9	56.3	52.8	57.4
HPD 3, Trial B	50.3	51.7	51.6	53.0
HPD 4, Trial A	50.4	52.3	51.6	53.4
HPD 4, Trial B	55.5	60.3	53.5	54.3
HPD 5, Trial A	53.0	55.9	53.6	56.4
HPD 5, Trial B	53.6	51.3	54.6	52.1
Ear Specific Mean (SD)	53.2 (2.0)	55.5 (3.0)	53.6 (1.4)	55.5 (2.6)
Level Overall Mean (SD)	54.4 (2.7)		54.6 (2.2)	

Discussion

The overall mean IPIL value was 54.4 dB at 160 dBP and 54.6 dB at 170 dBP. Across ears, the individual trial mean IPIL values were found to vary as much as 10.0 dB at 160 dBP and 7.8 dB at 170 dBP. This may be due to a combination of inherent variance within the impulse system and/or variability in fit as a result of each HPD sample being fitted twice. Results indicate that while the overall mean IPIL values were within 0.2 dB of each other, a greater variety of attenuation was present in the individual trials at the 160 dBP level compared to 170 dBP. This is noted with a larger SD at the 160 dBP (2.7 dB) nominal level compared to that at the 170 dBP (2.2 dB) nominal level.

It is important to note that these results do not guarantee similar Pura-Fit® Uncorded product performance across all users and environments. Product performance may be impacted by factors such as variability in physical fit of the device and HPD configuration (e.g., single, double- or triple- configuration, and/or simultaneous use with other head worn protective devices such as helmets or eye protection).

Conclusions

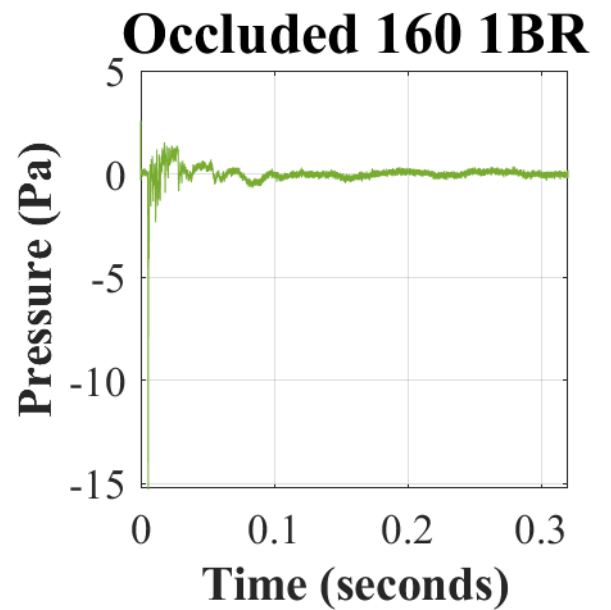
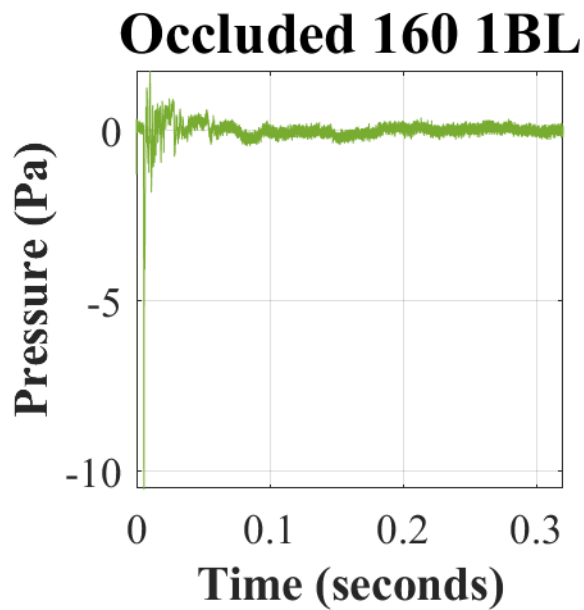
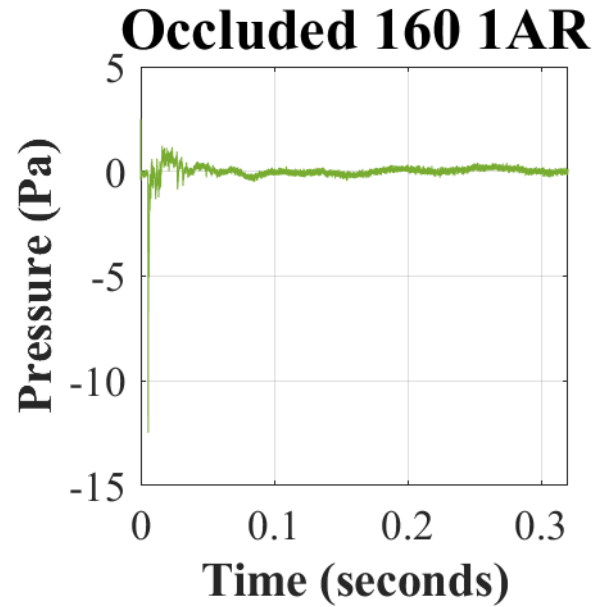
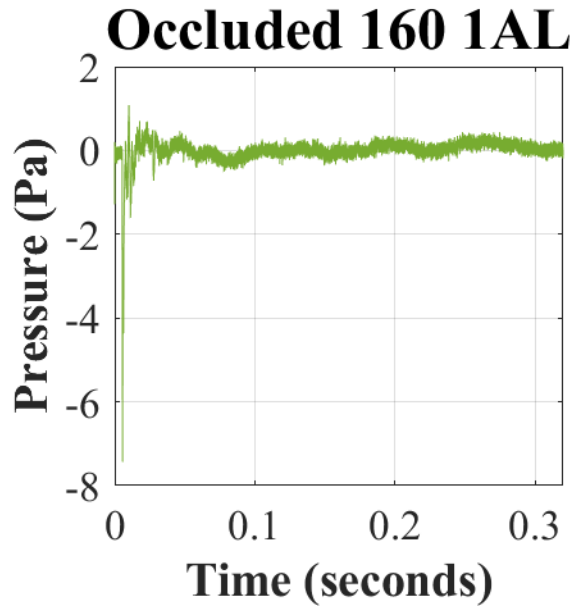
This report described the determination of the mean impulse peak insertion loss (IPIL) values provided by the Moldex® Pura-Fit® Uncorded Earplug (Pura-Fit® Uncorded) at 160 dBP and 170 dBP nominal levels. The calculated overall mean (SD) IPIL values for the Pura-Fit® Uncorded were found to be 54.4 (2.7) dB at 160 dBP and 54.6 (2.2) dB at 170 dBP. The results of this effort imply that when properly fit and functional, the Moldex® Pura-Fit® Uncorded Earplug will adequately protect (i.e.,

reduce the exposure below 140 dBP) the user from impulses below 180 dBP. This value is based on the 180 dBP limit of the applicability of IPIL values measured at 170 dBP in MIL-STD-1474E B.5.3.3 (Department of Defense, 2015).

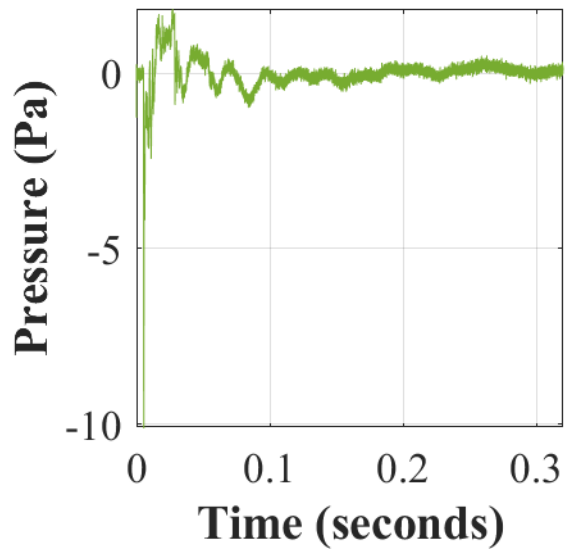
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- Office of the Under Secretary of Defense for Personnel and Readiness (2019). *DoD Instruction 6055.12 Hearing Conservation Program (HCP)*. Department of Defense.

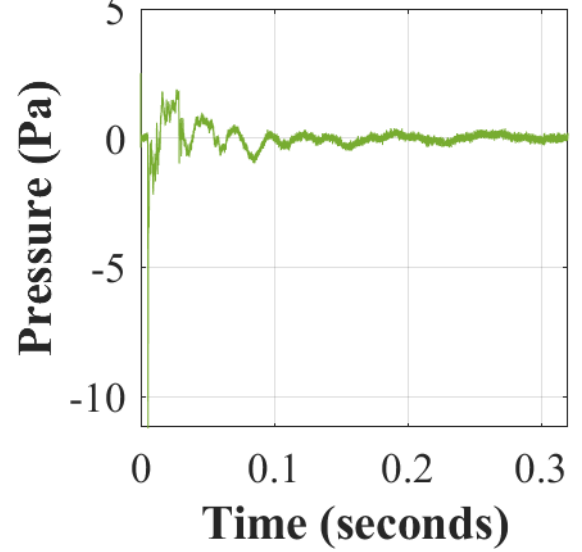
Appendix A. Recorded occluded (closed-ear) waveforms (in pascals (Pa)) over time (in seconds (s)) in response to 160 dBP with the Pura-Fit® Uncorded Earplugs.



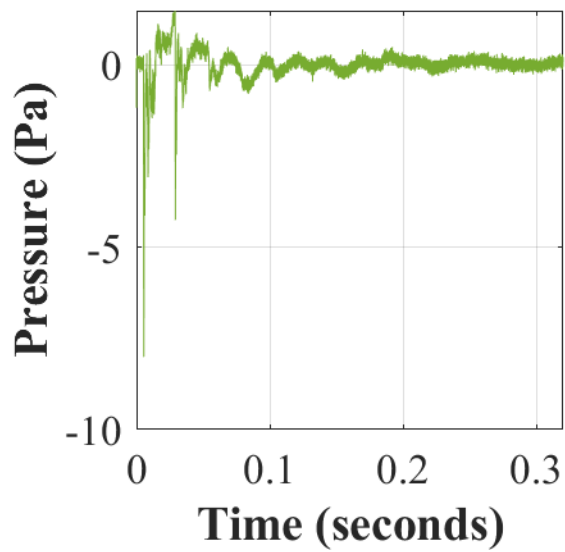
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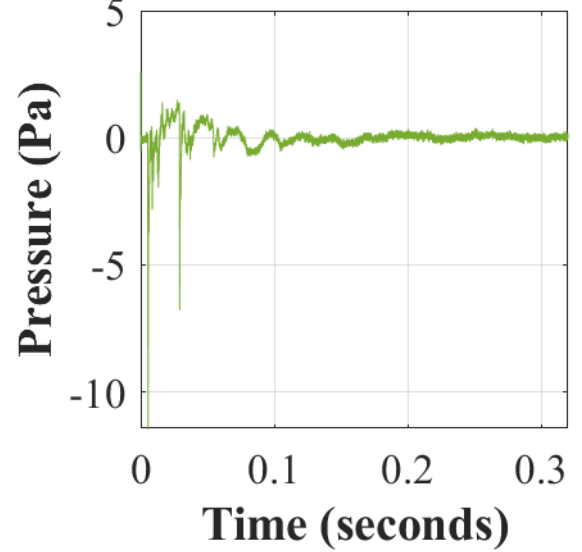
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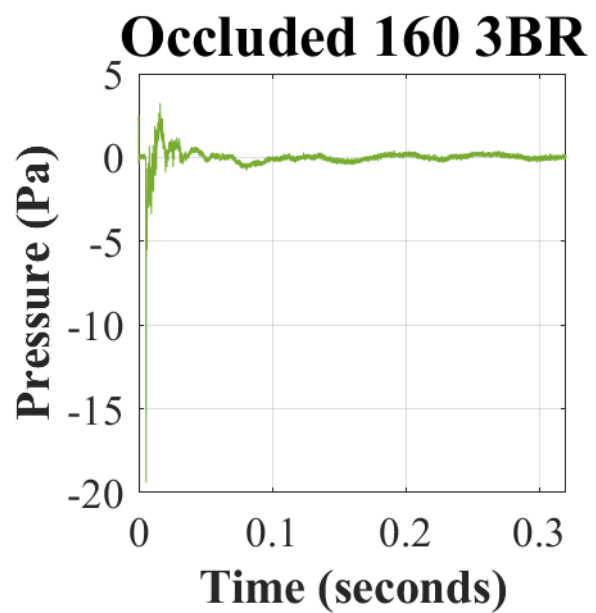
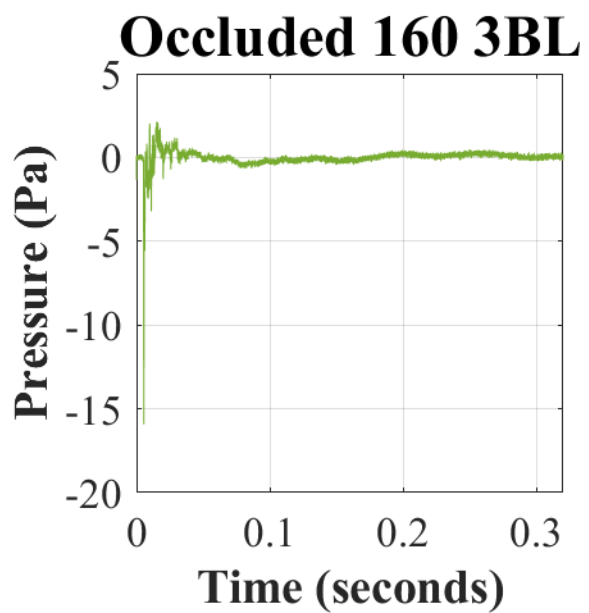
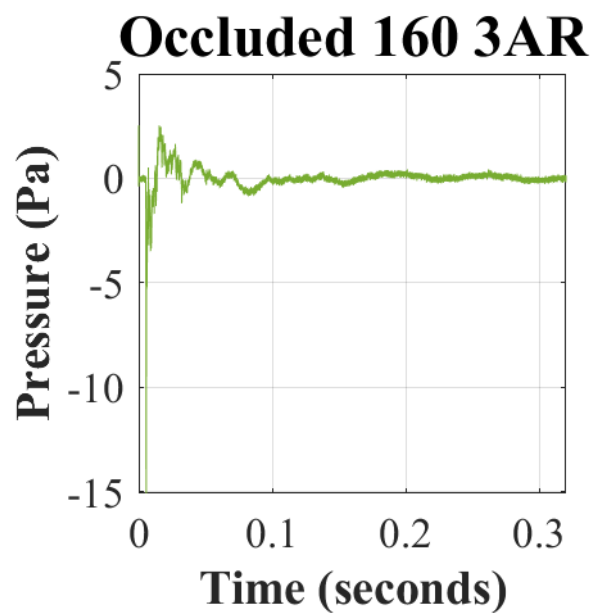
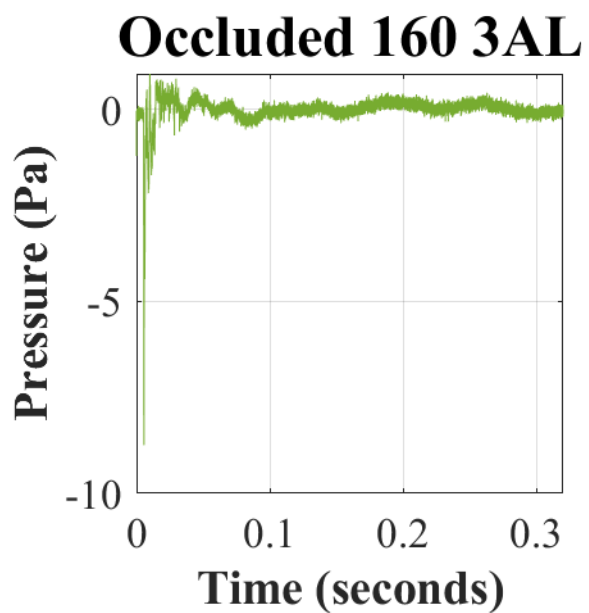


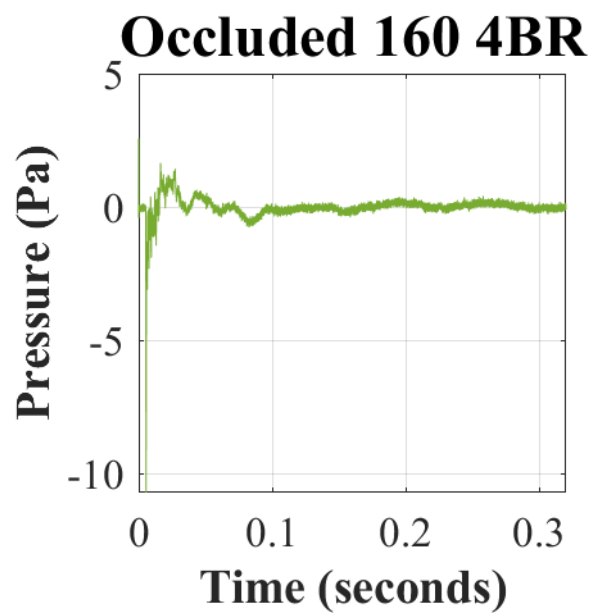
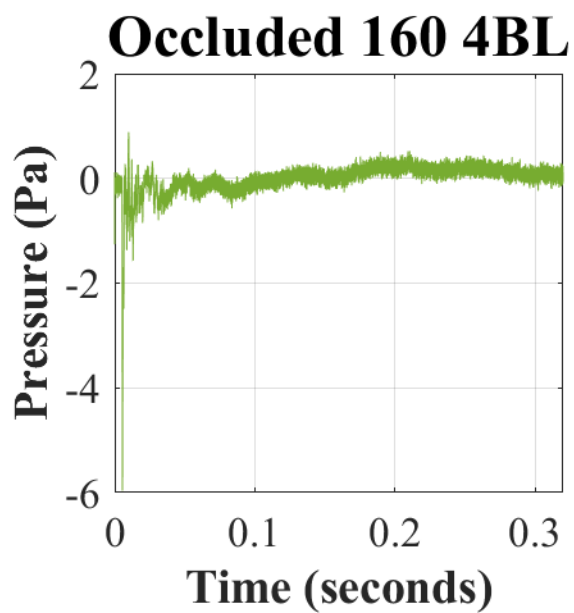
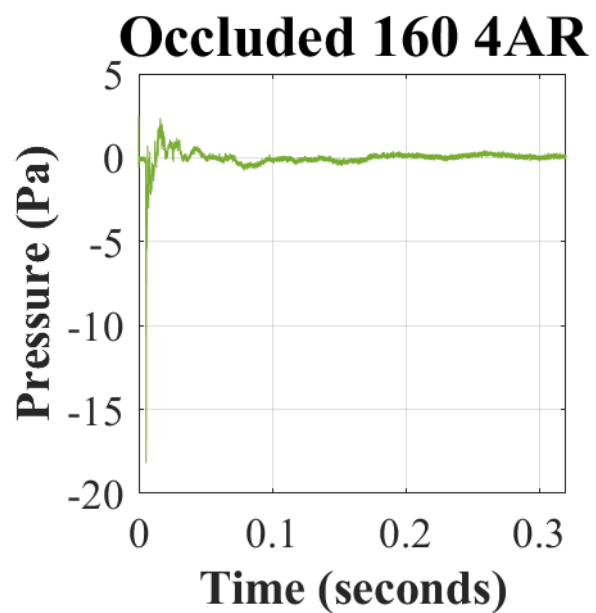
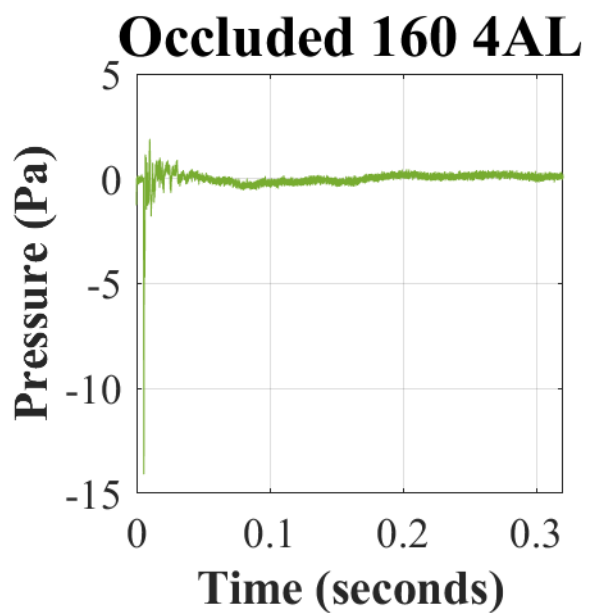
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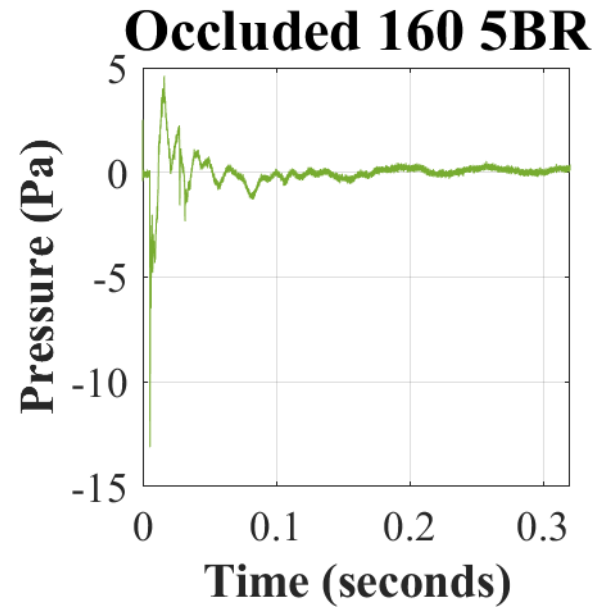
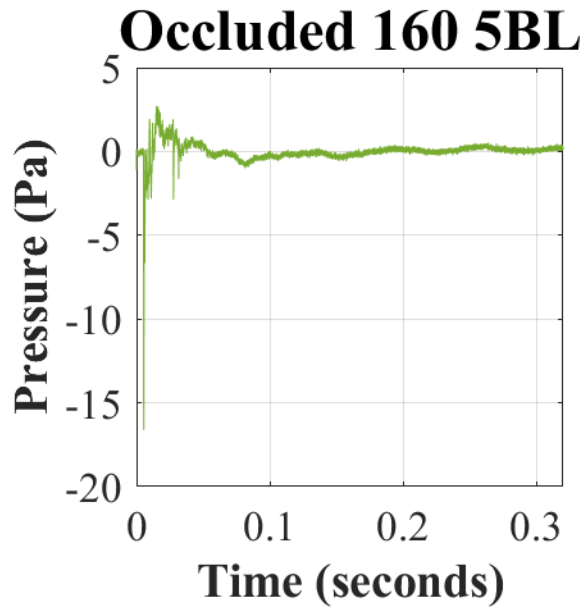
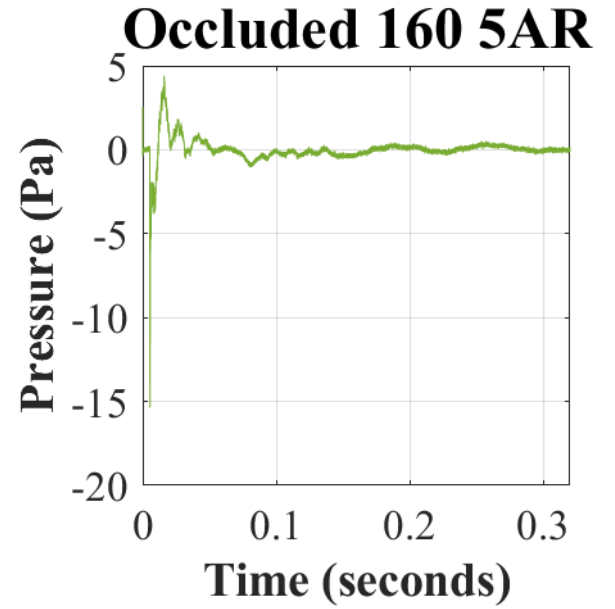
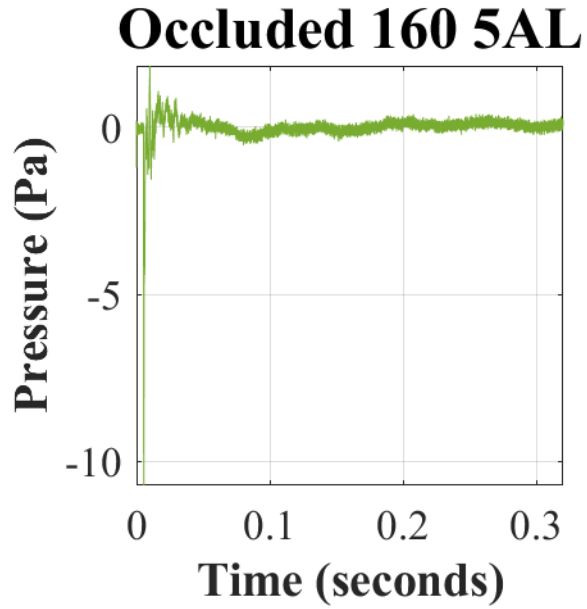


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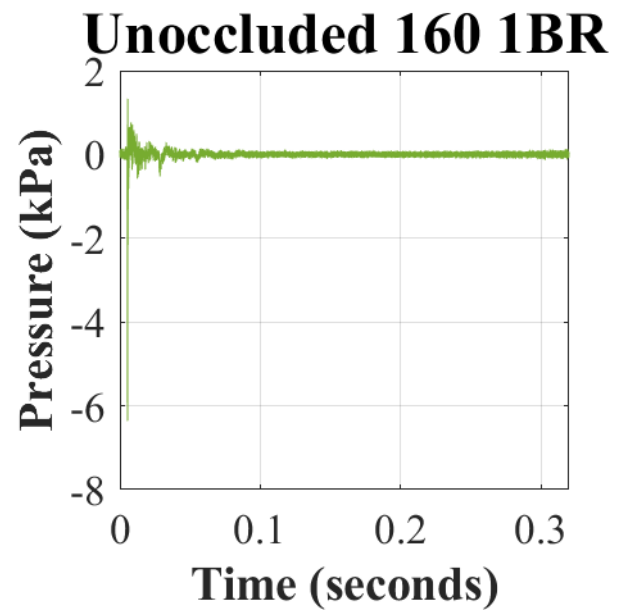
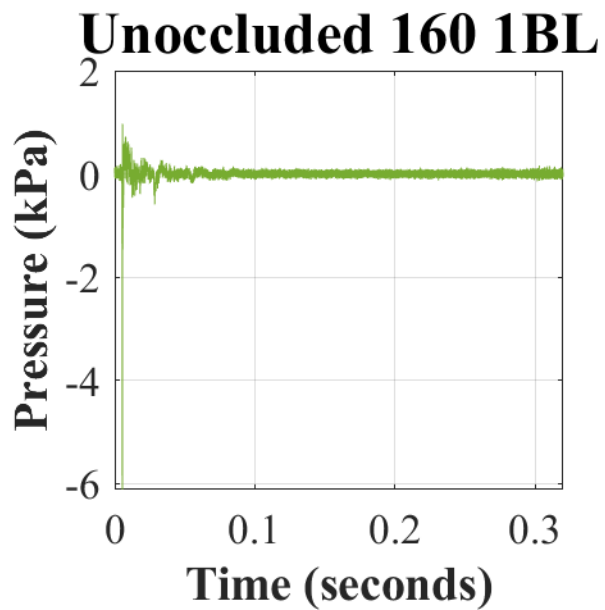
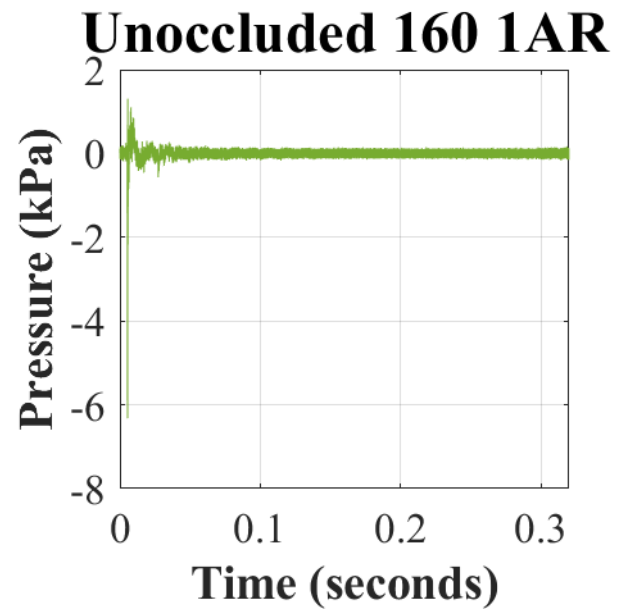
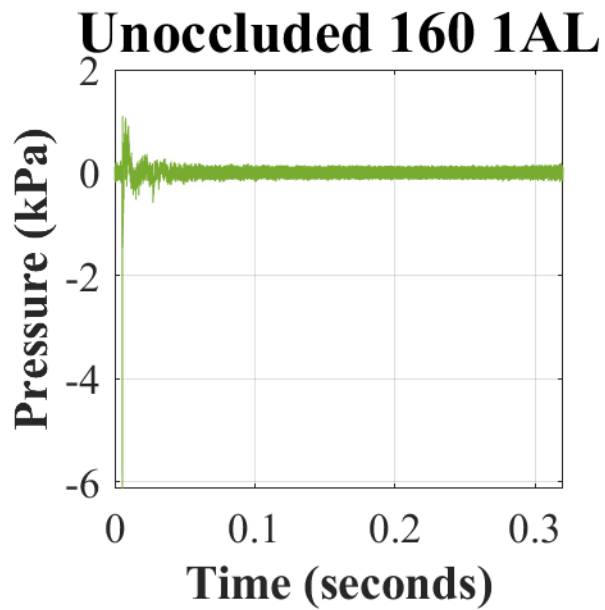


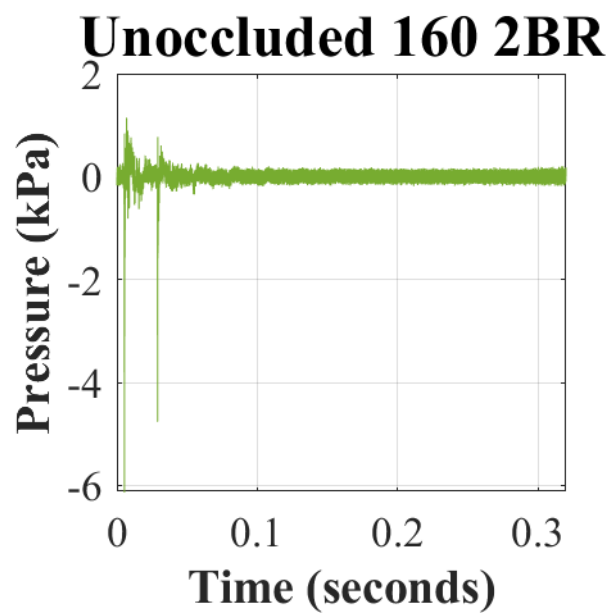
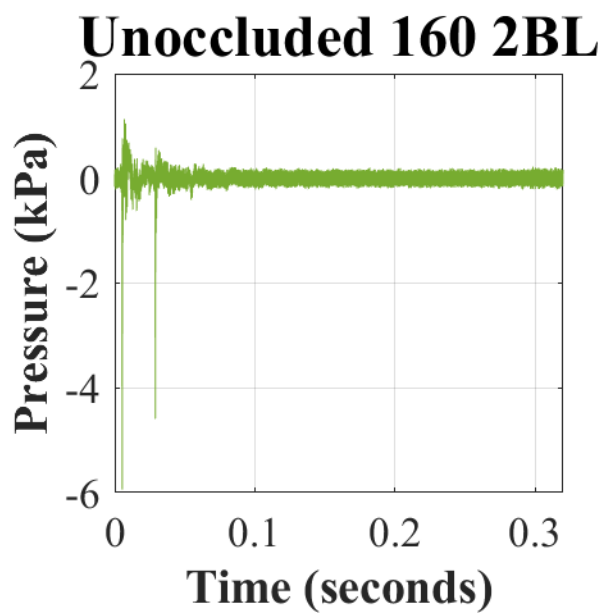
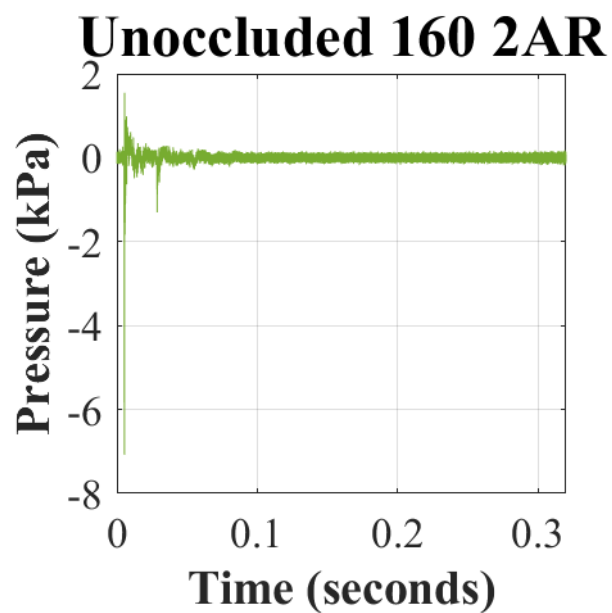
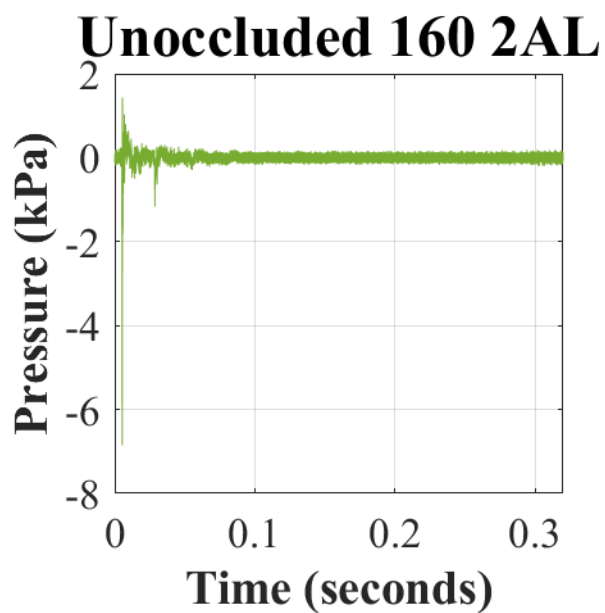


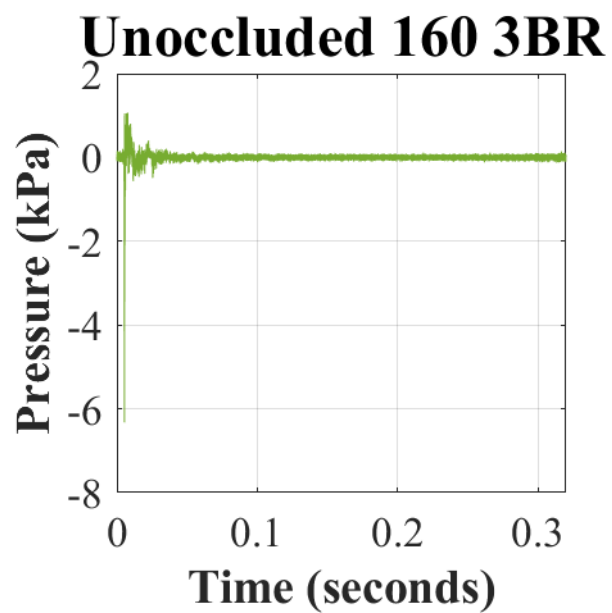
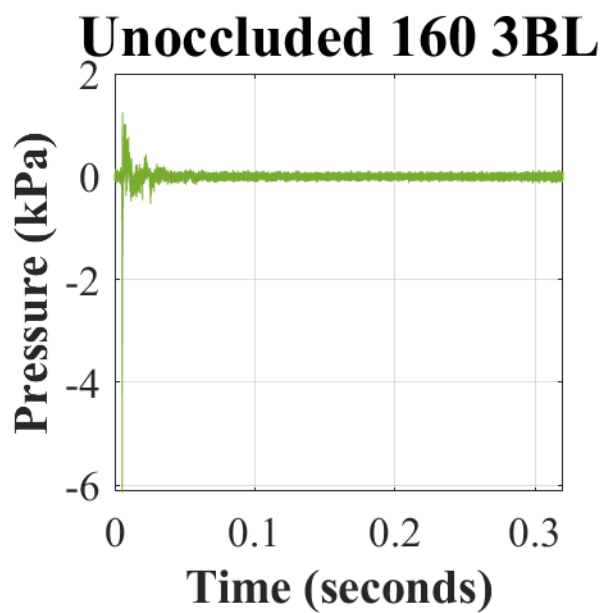
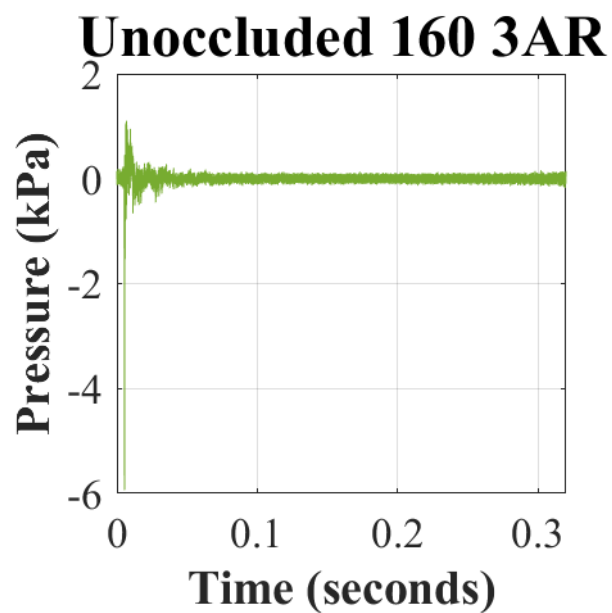
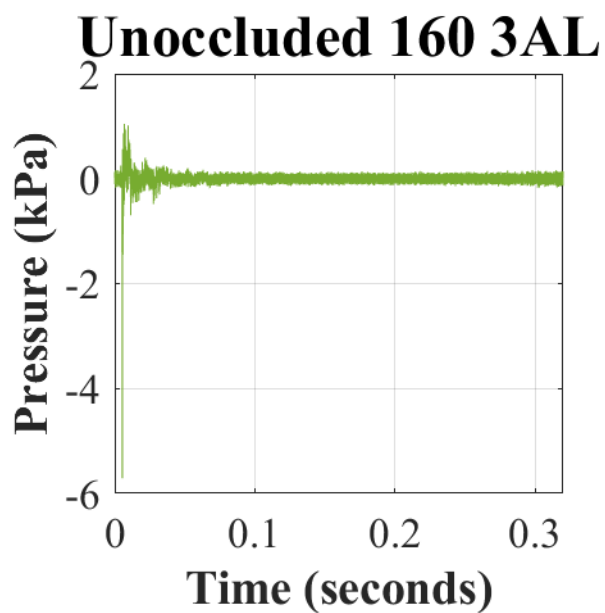


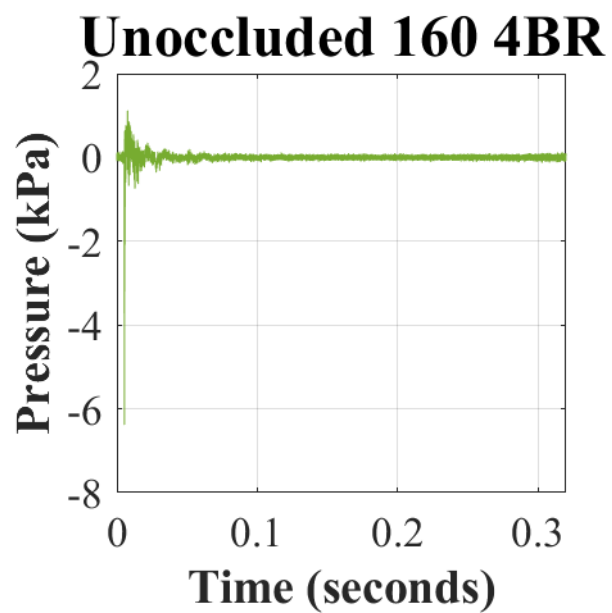
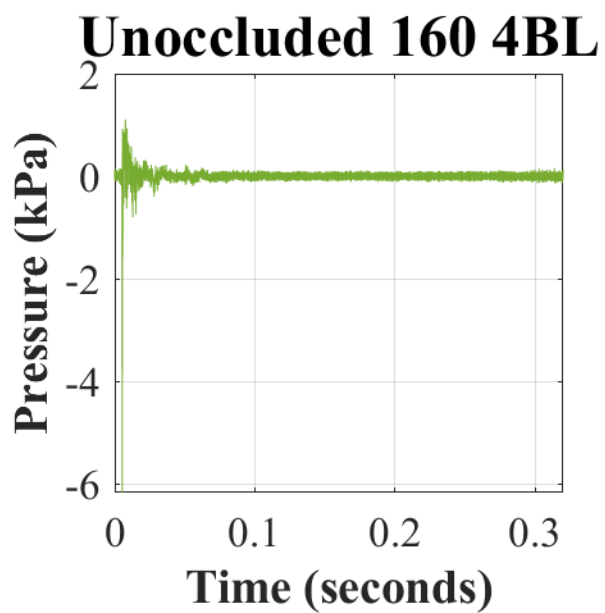
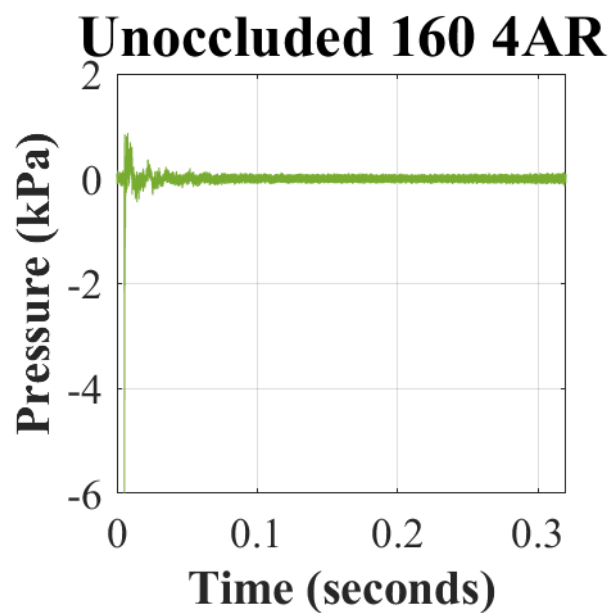
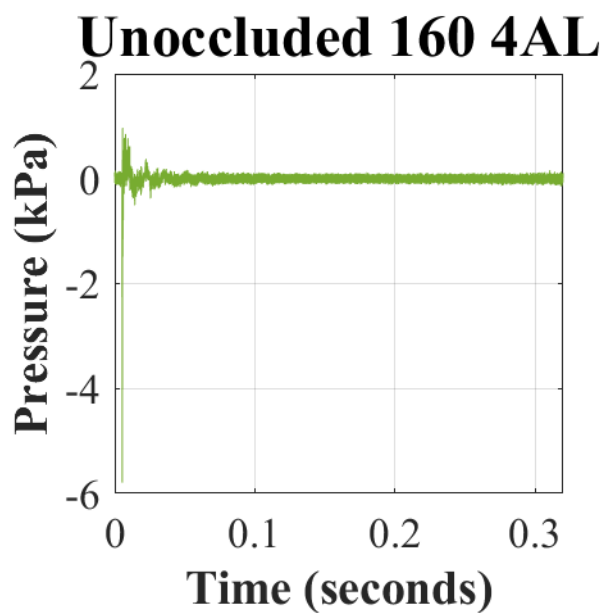
Note. The naming convention for all occluded waveforms is “Occluded LvL NnX”, where ‘Occluded’ is the test condition (i.e., ATF has the HPD donned), ‘LvL’ is the nominal test level (i.e., 160 or 170 dBP), ‘N’ is the sample number (i.e., 1 to 5) of the device tested, ‘n’ is the trial (i.e., A or B) indicating HPD fit (i.e., first or second, respectively), and ‘X’ indicates from what ATF microphone the recording is from (i.e., right (R) or left (L) pinnae).

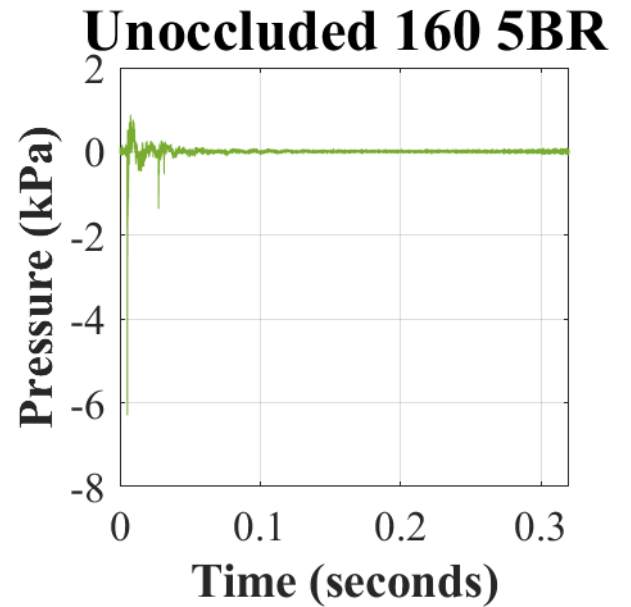
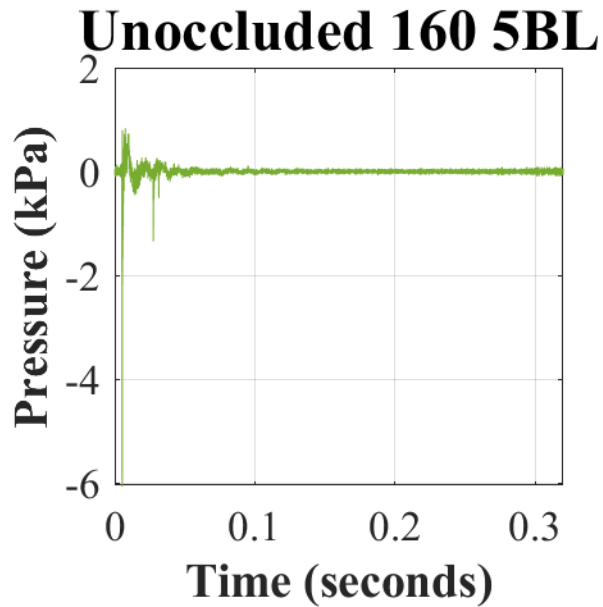
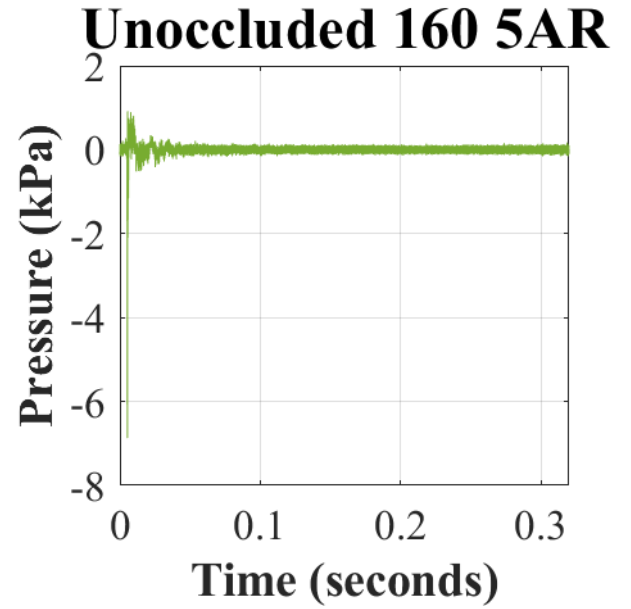
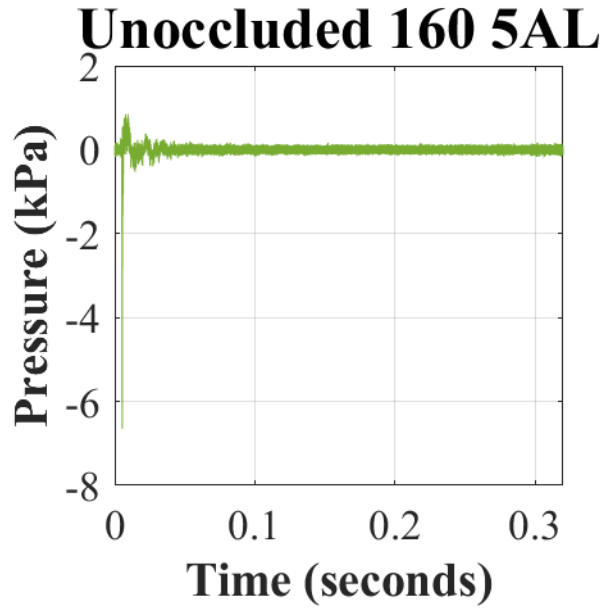
Appendix B. Estimated unoccluded (open-ear) waveforms (in kilopascals (kPa)) over time (in seconds (s)) in response to 160 dBp with the Pura-Fit® Uncorded Earplugs.





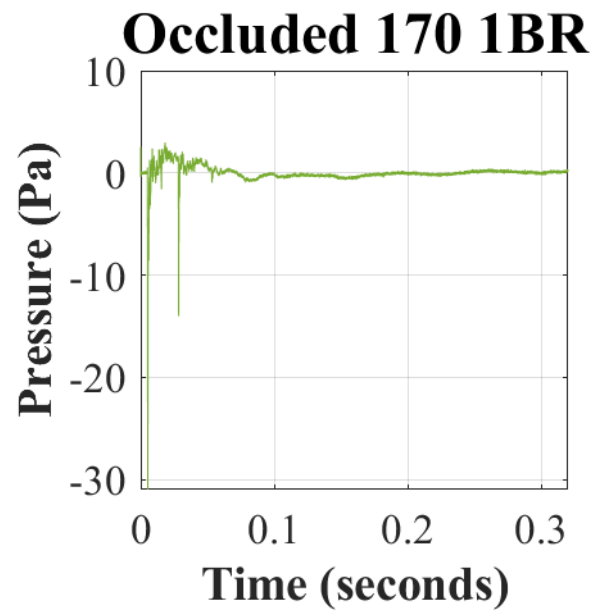
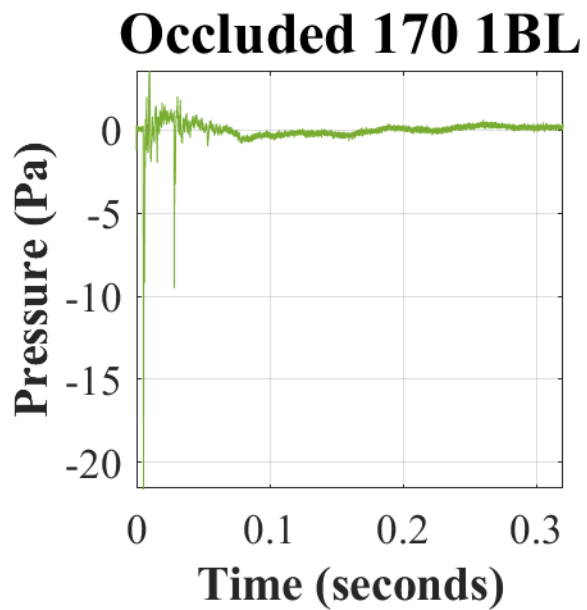
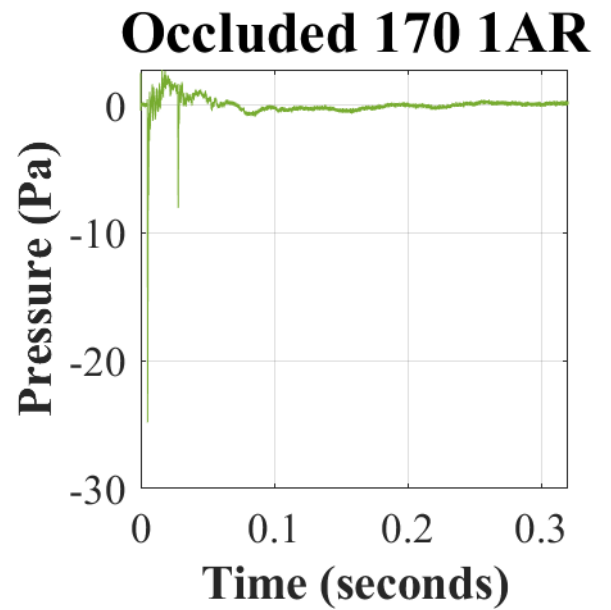
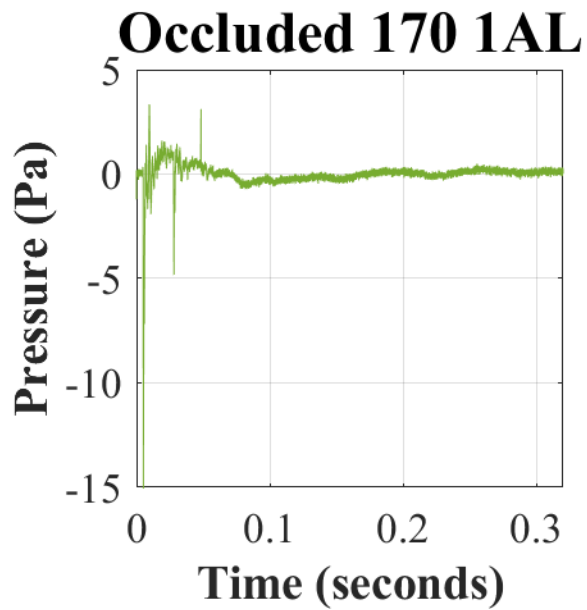


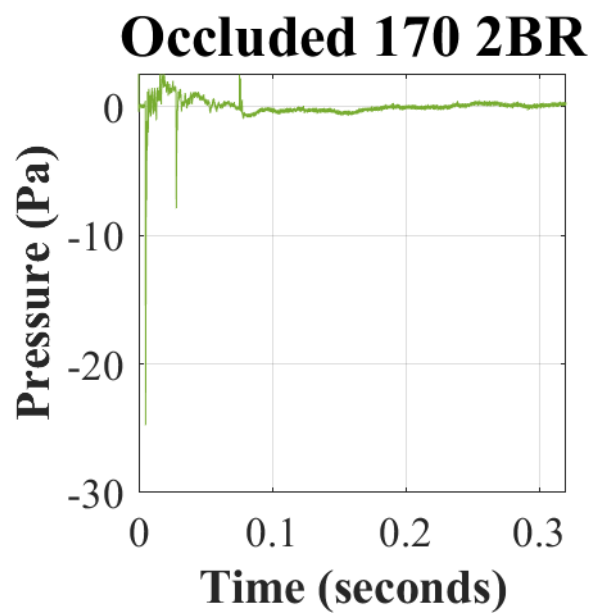
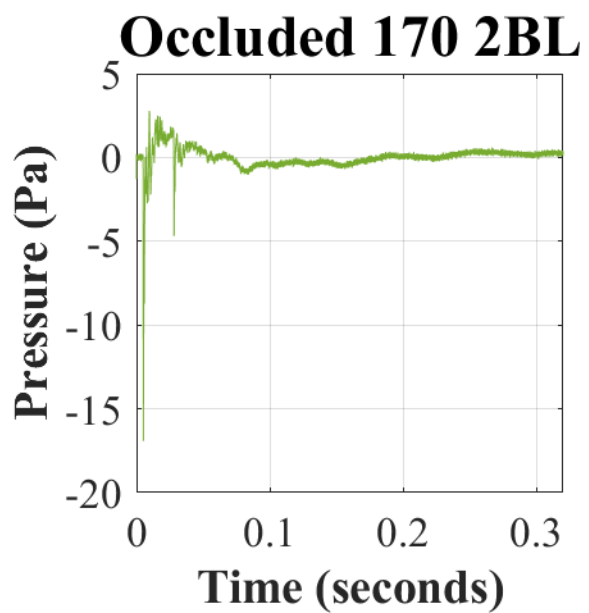
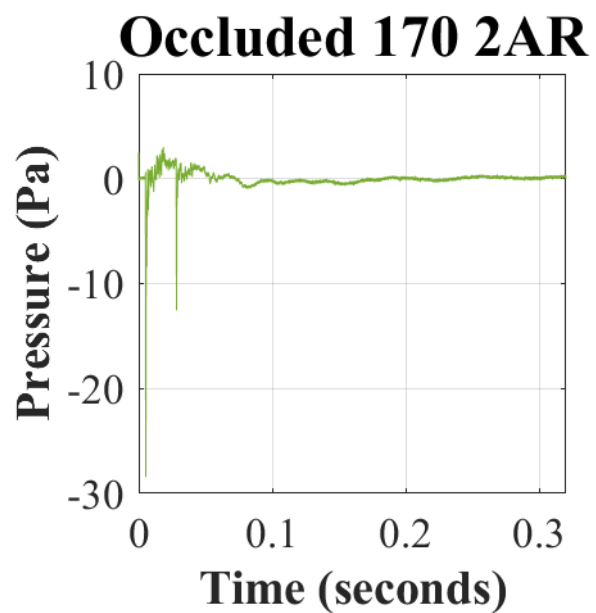
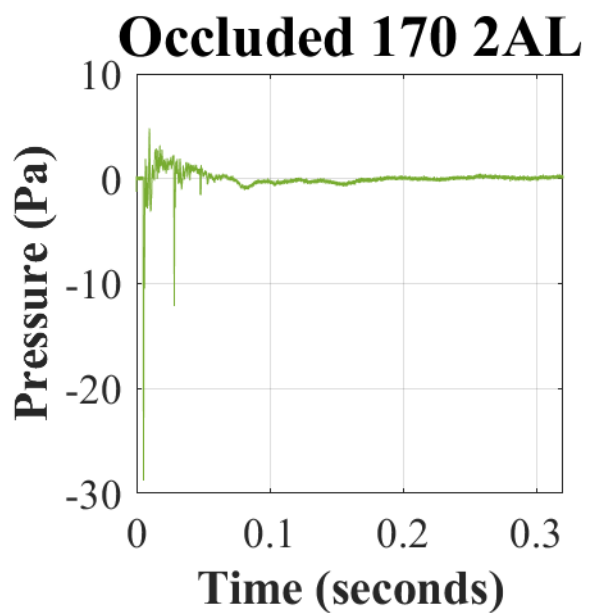


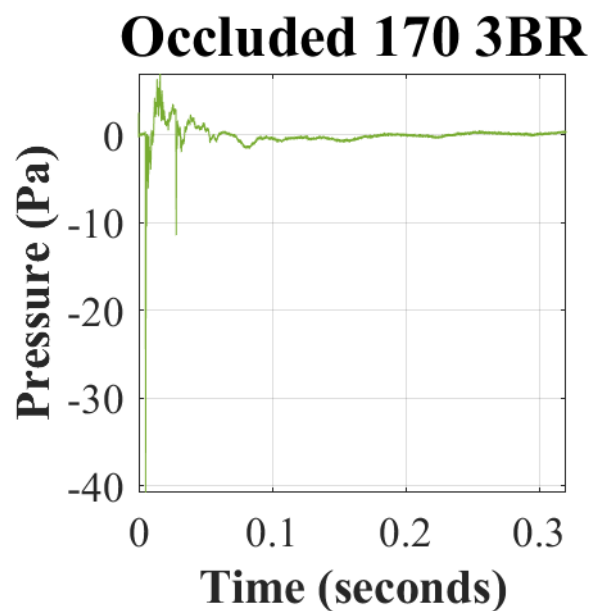
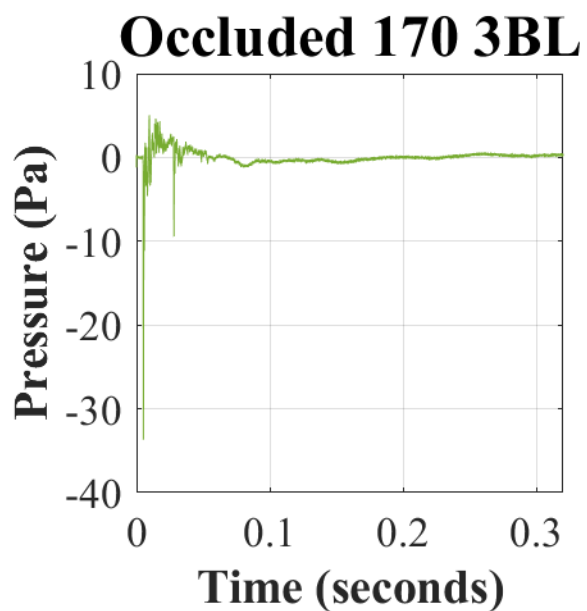
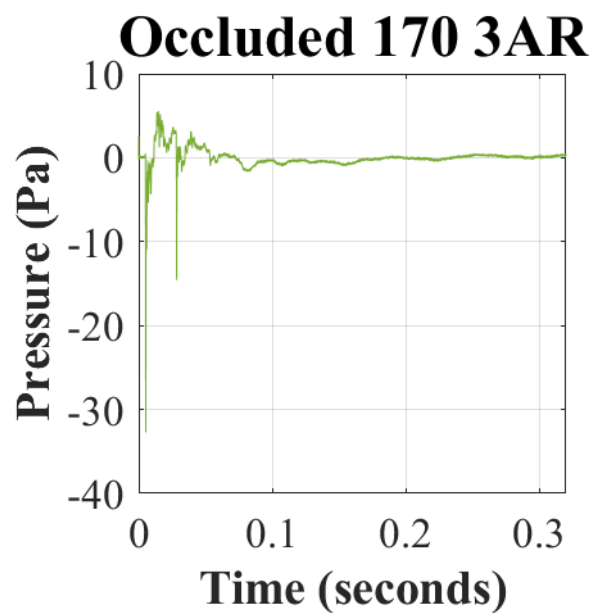
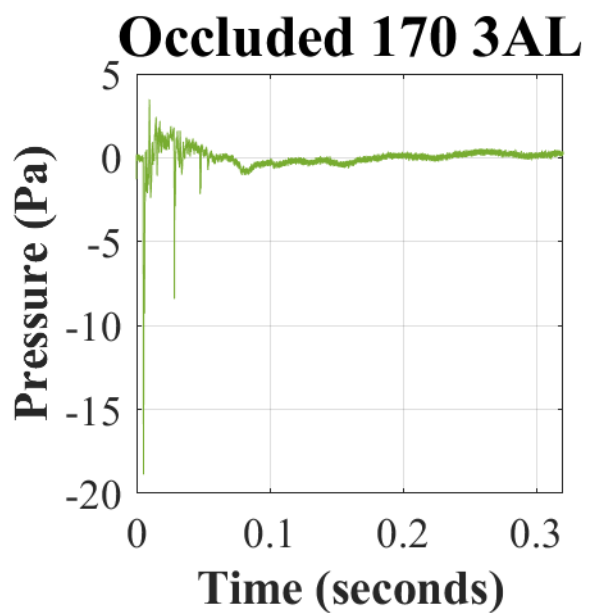


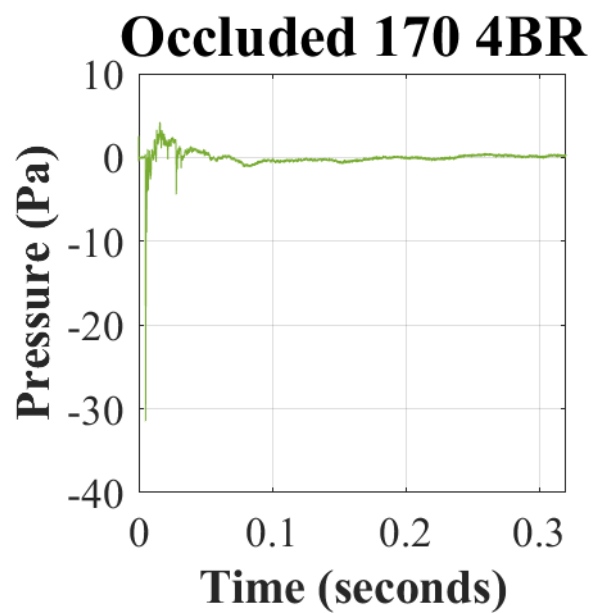
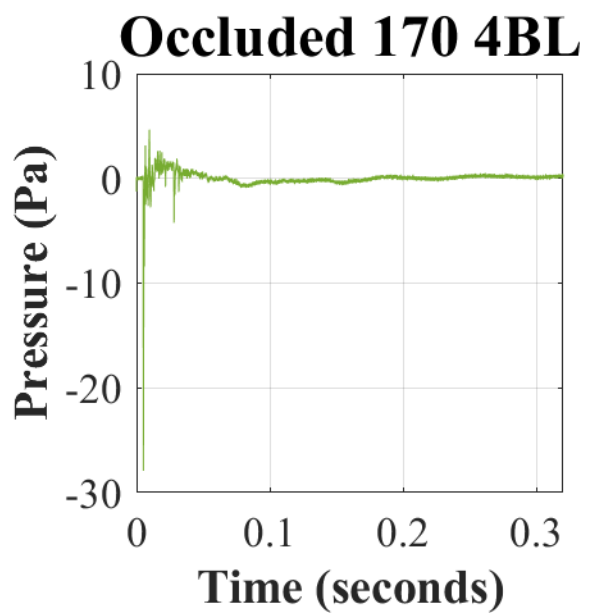
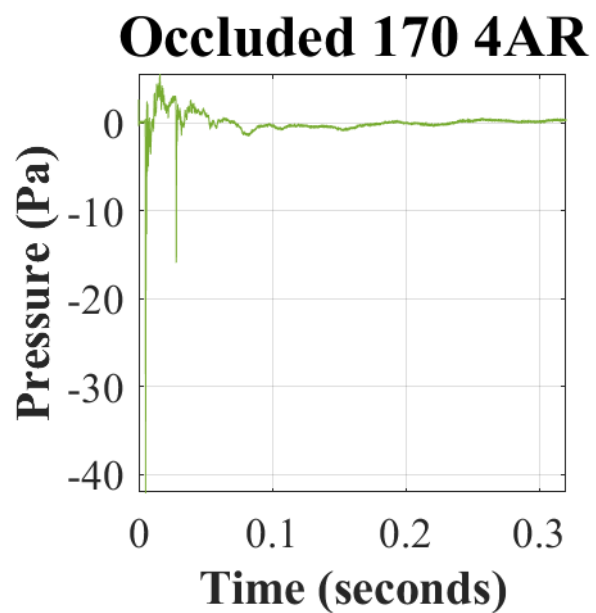
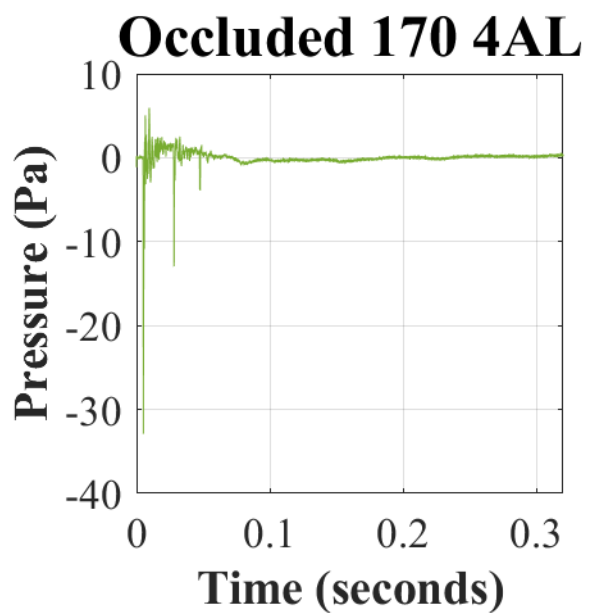
Note. The naming convention for all occluded waveforms is “Unoccluded LvL NnX”, where ‘Unoccluded’ is the test condition (i.e., ATF has the HPD doffed), ‘LvL’ is the nominal test level (i.e., 160 or 170 dBP), ‘N’ is the sample number (i.e., 1 to 5) of the device tested, ‘n’ is the trial (i.e., A or B) indicating HPD fit (i.e., first or second, respectively), and ‘X’ indicates from what ATF microphone the recording is from (i.e., right (R) or left (L) pinnae).

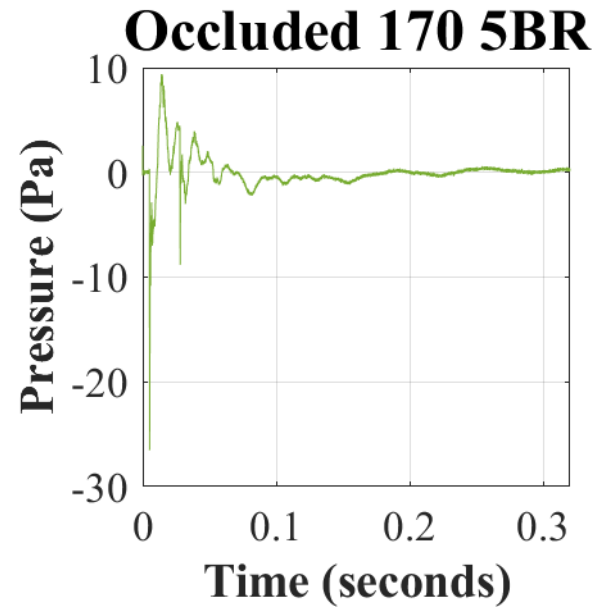
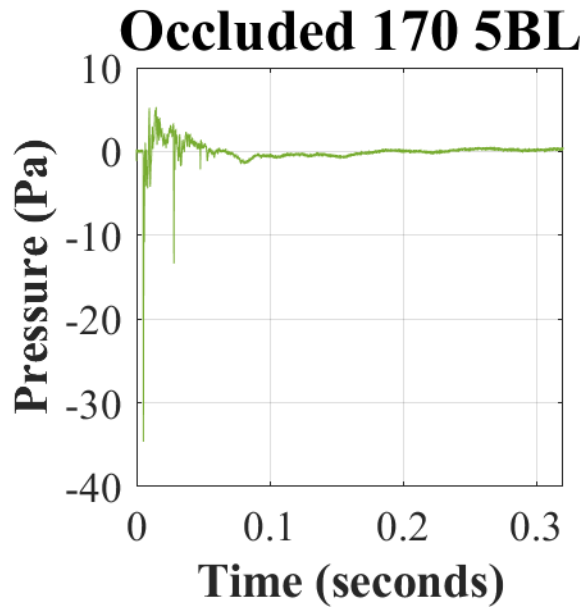
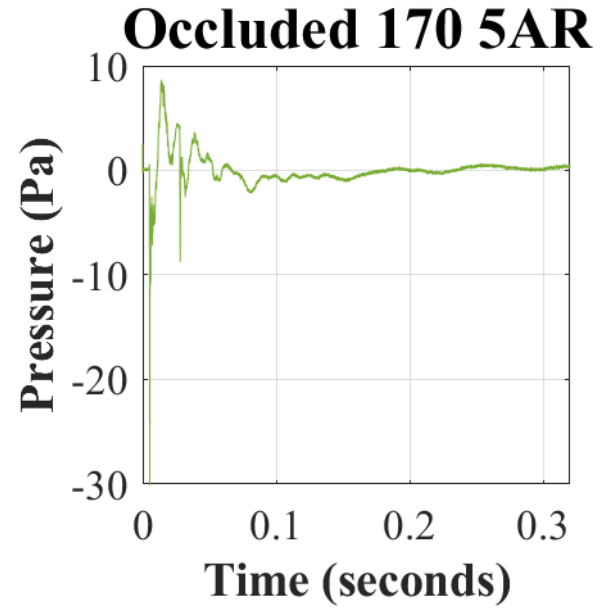
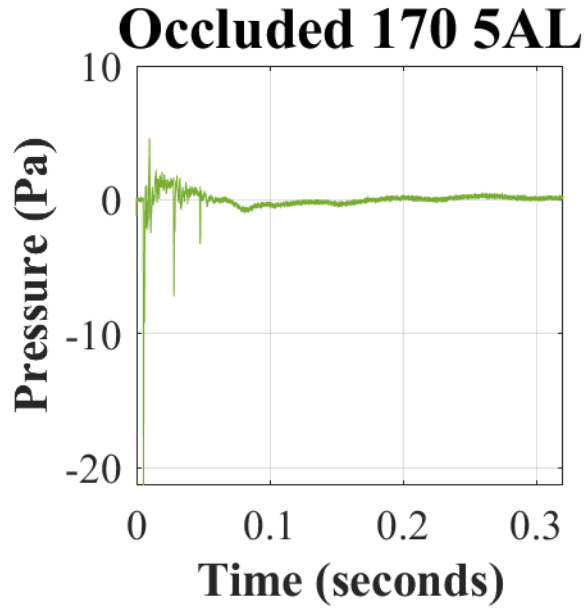
Appendix C. Recorded occluded (closed-ear) waveforms (in pascals (Pa)) over time (in seconds (s)) in response to 170 dBp with the Pura-Fit[®] Uncorded Earplugs.





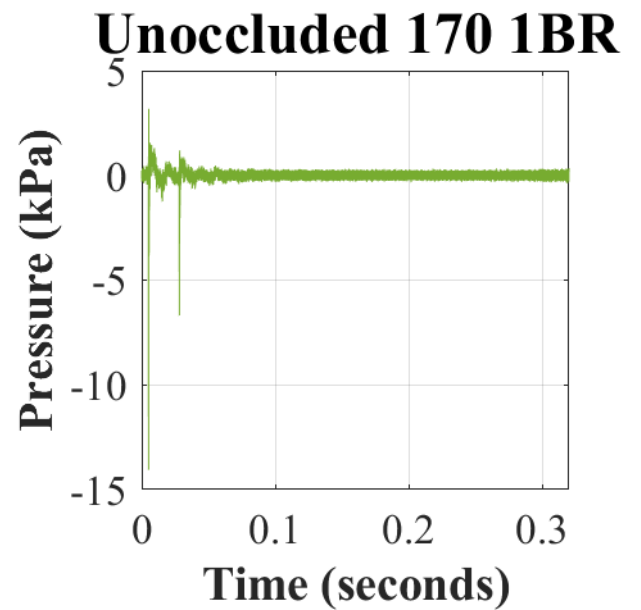
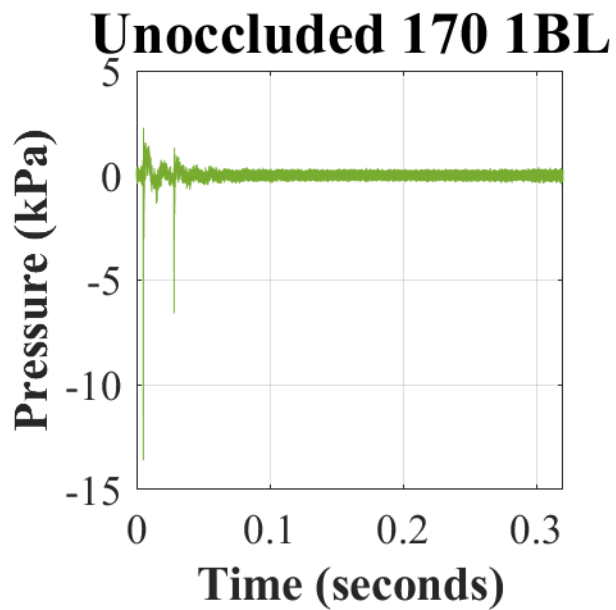
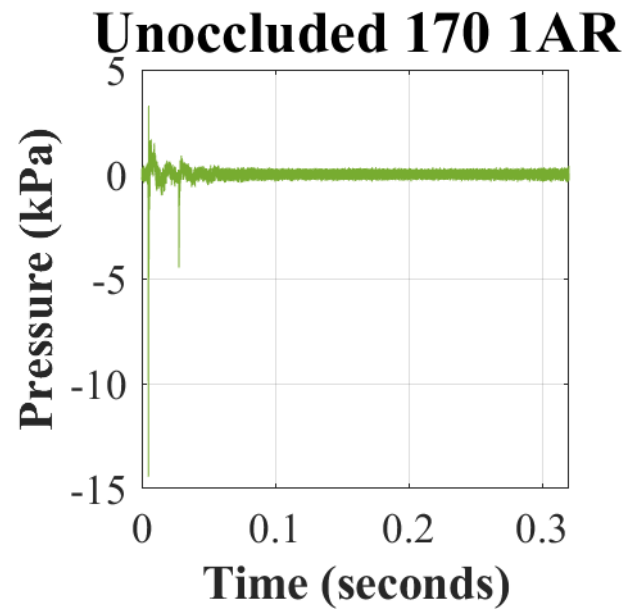
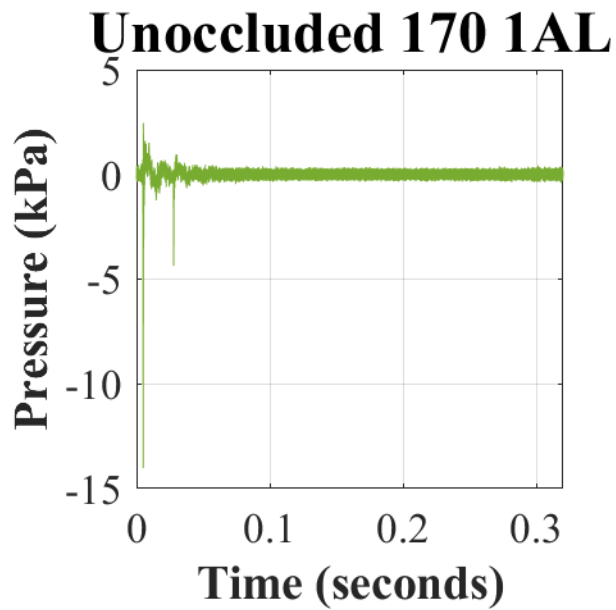


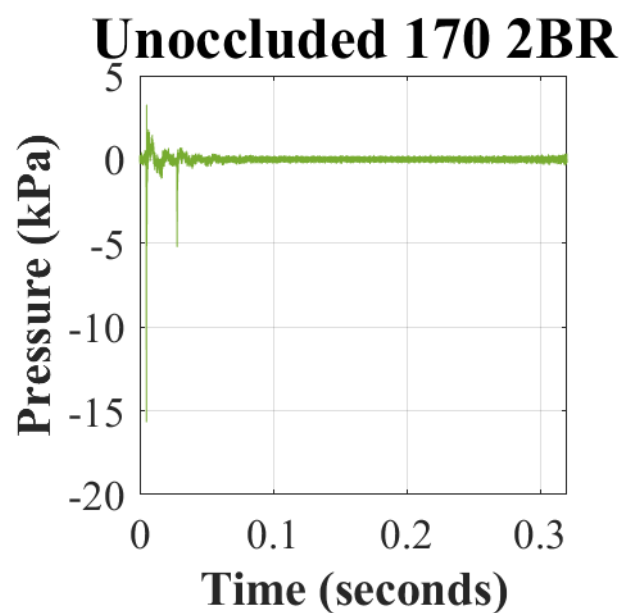
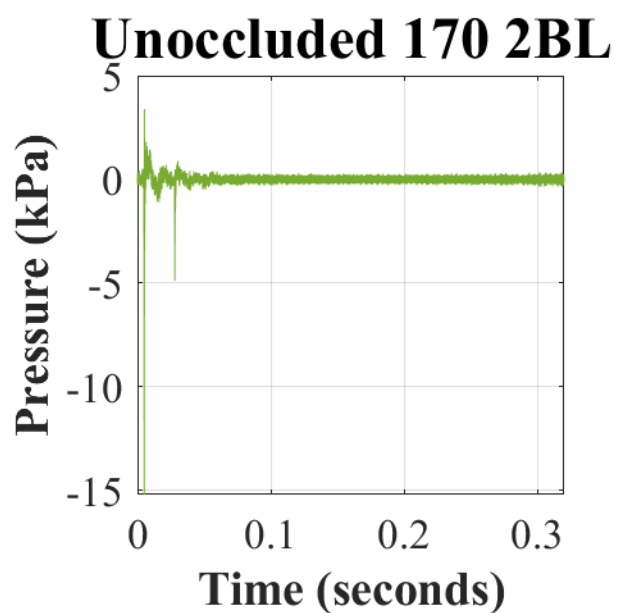
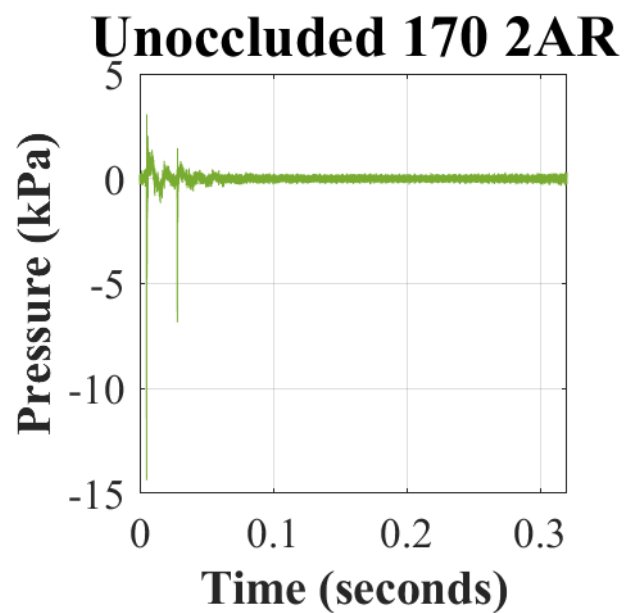
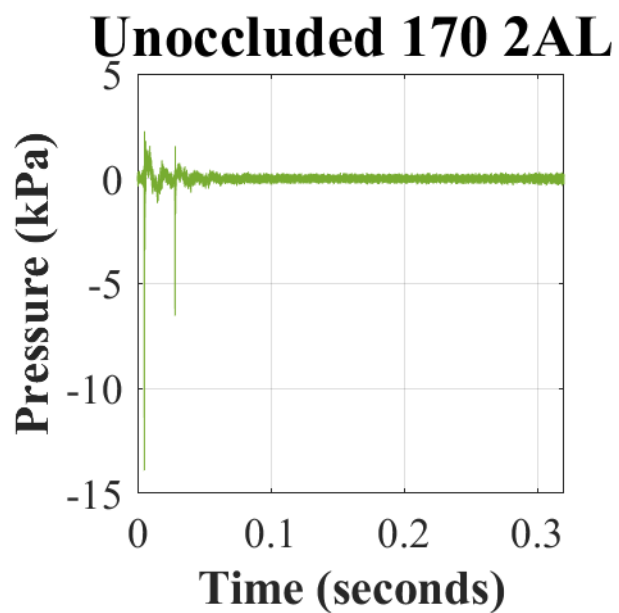


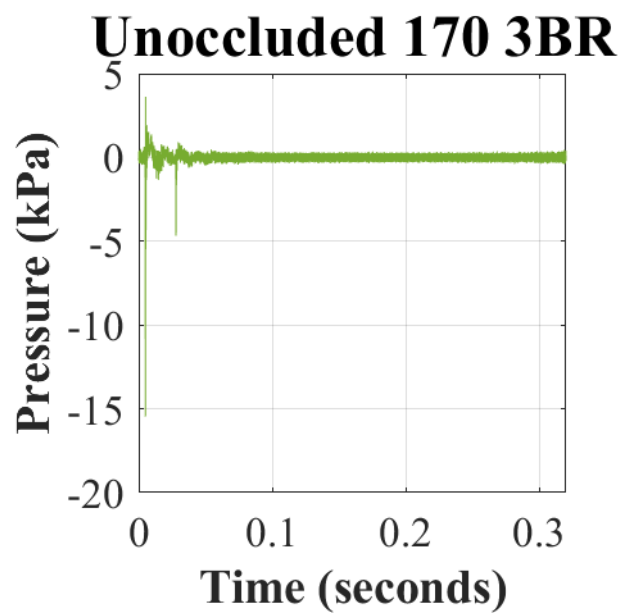
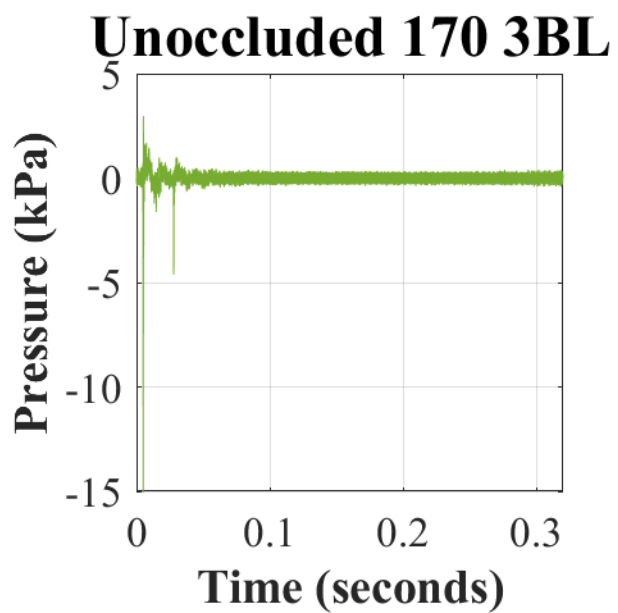
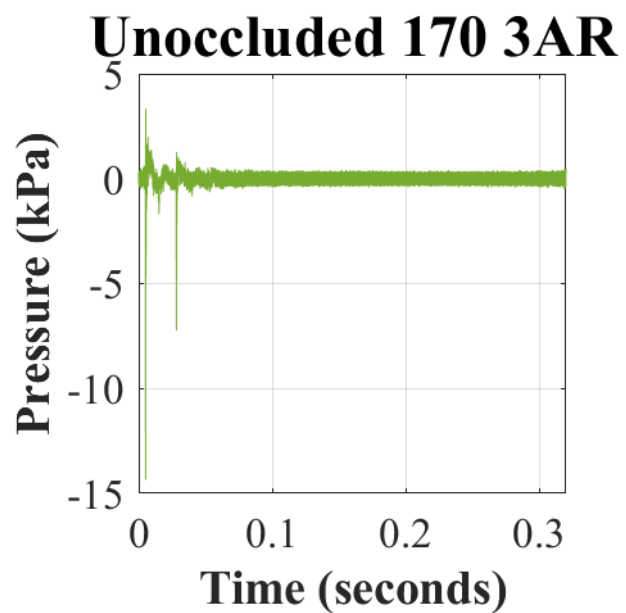
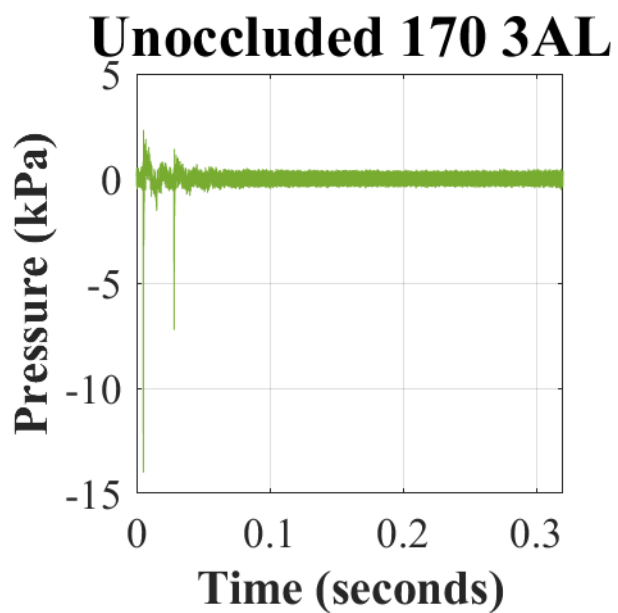


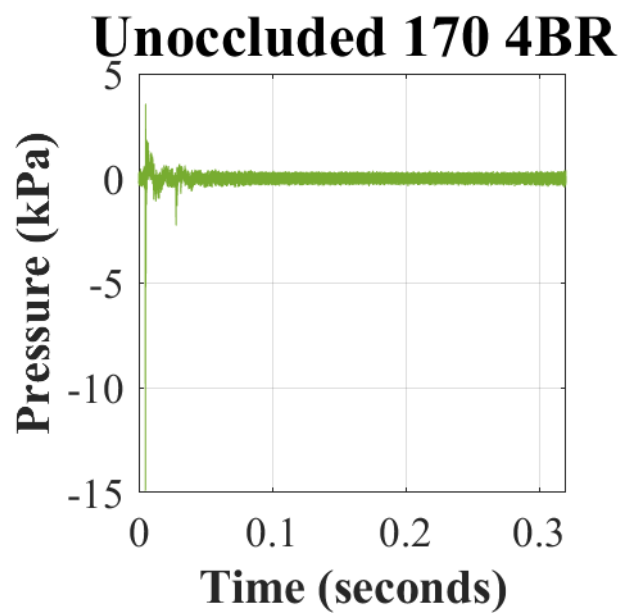
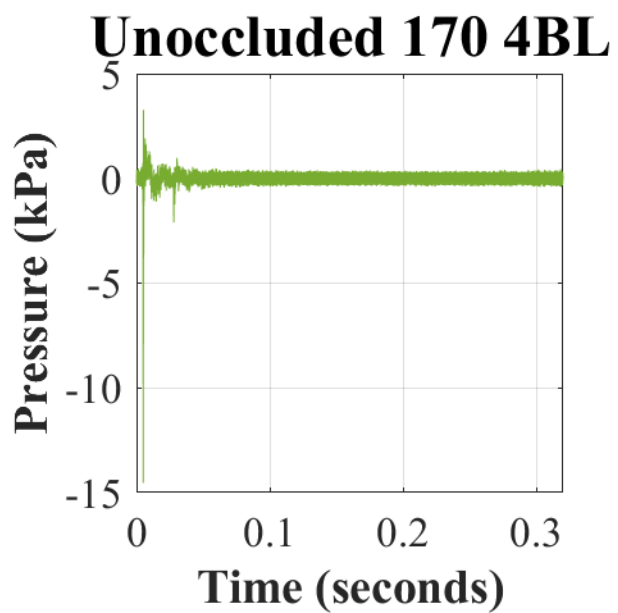
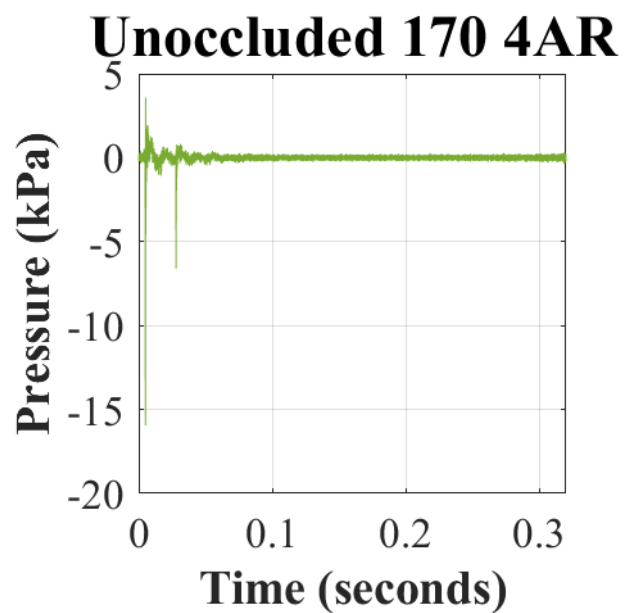
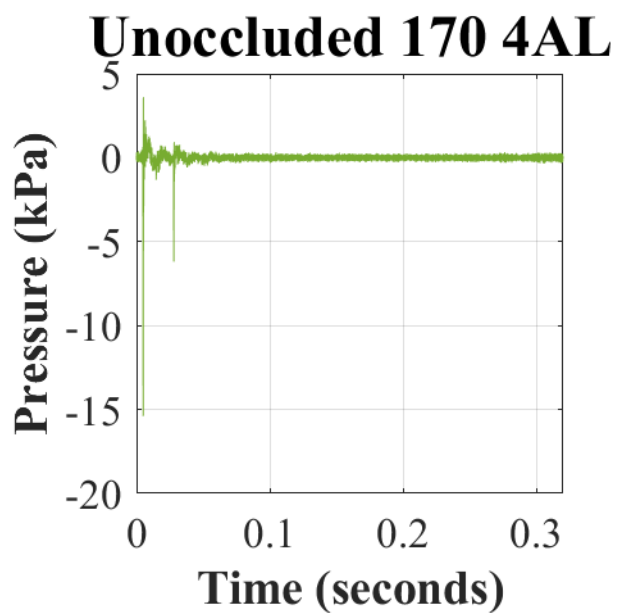
Note. The naming convention for all occluded waveforms is “Occluded LvL NnX”, where ‘Occluded’ is the test condition (i.e., ATF has the HPD donned), ‘LvL’ is the nominal test level (i.e., 160 or 170 dBp), ‘N’ is the sample number (i.e., 1 to 5) of the device tested, ‘n’ is the trial (i.e., A or B) indicating HPD fit (i.e., first or second, respectively), and ‘X’ indicates from what ATF microphone the recording is from (i.e., right (R) or left (L) pinnae).

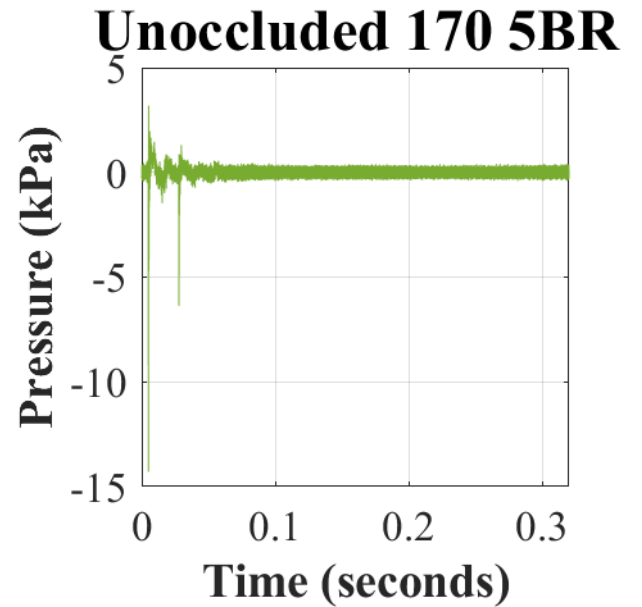
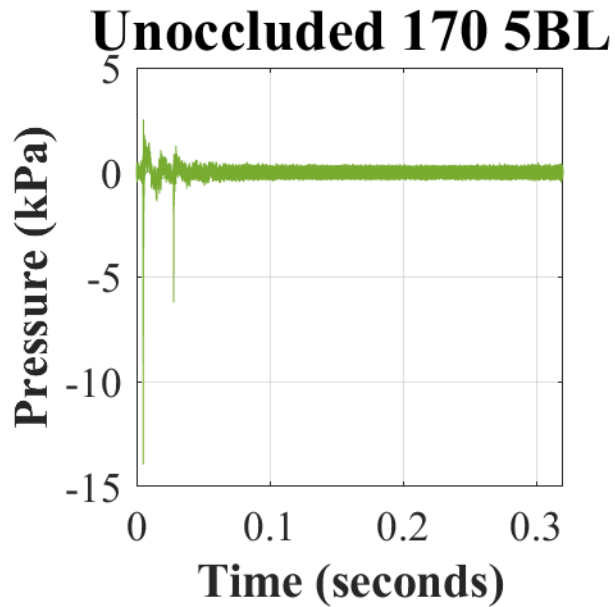
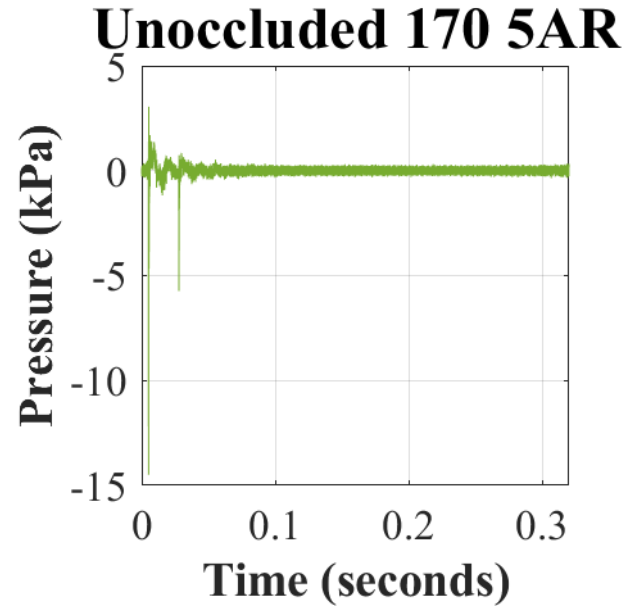
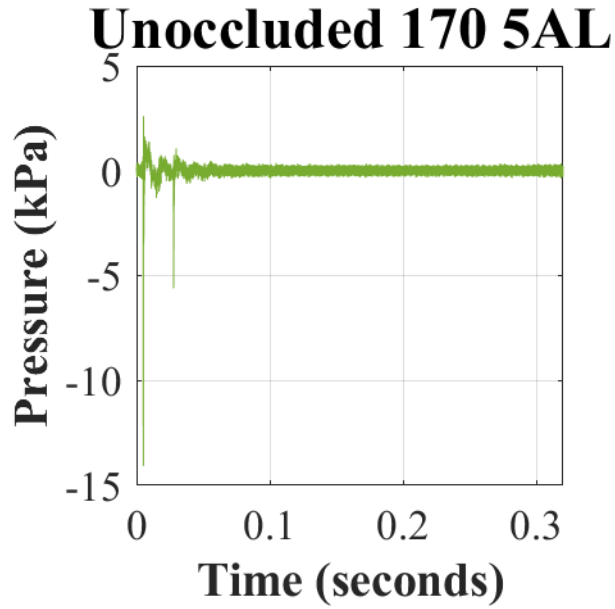
Appendix D. Estimated unoccluded (open-ear) waveforms (in kilopascals (kPa)) over time (in seconds (s)) in response to 170 dBp with the Pura-Fit® Uncorded Earplugs.





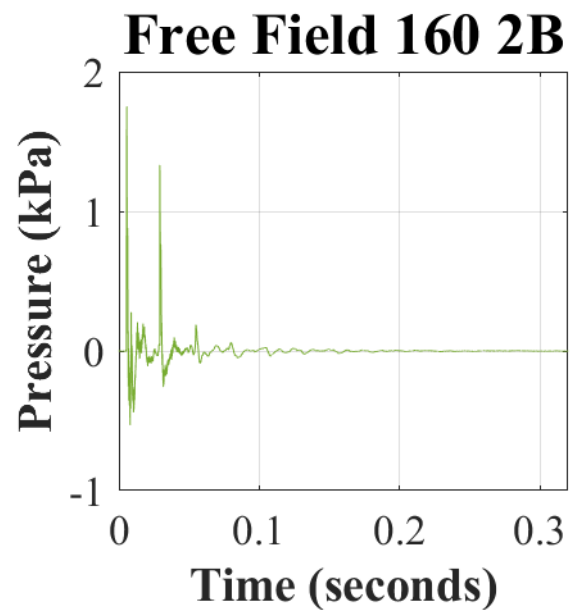
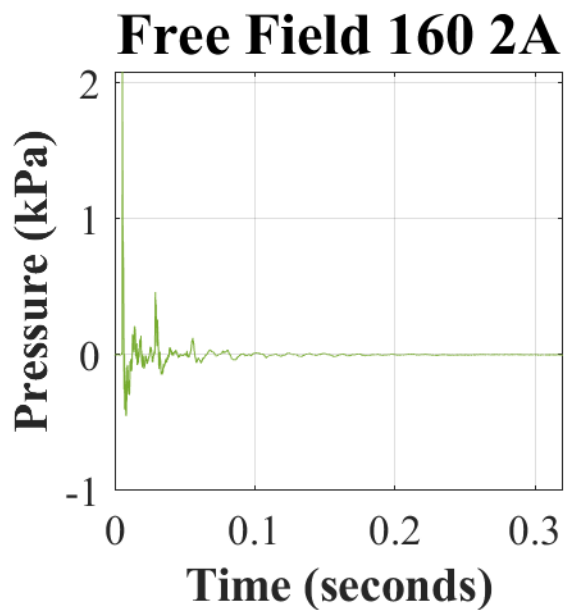
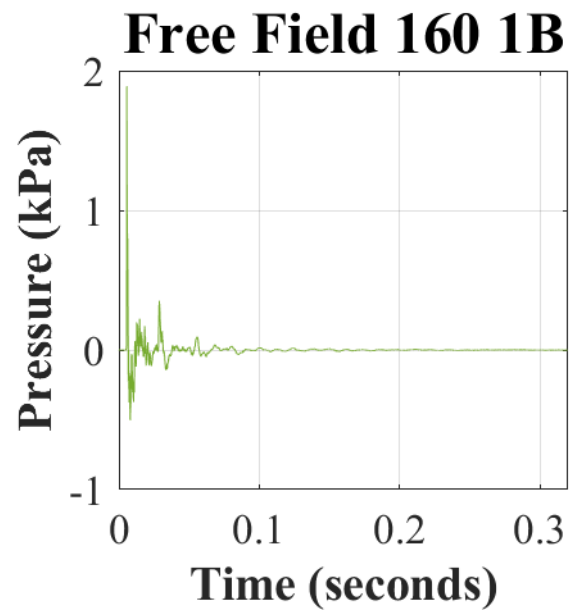
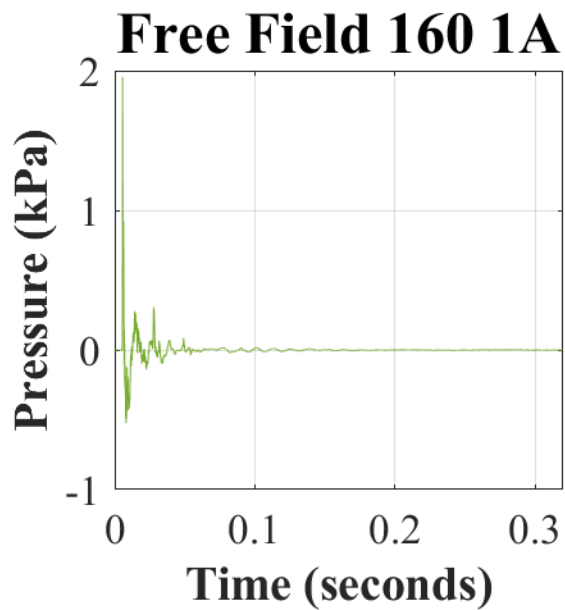


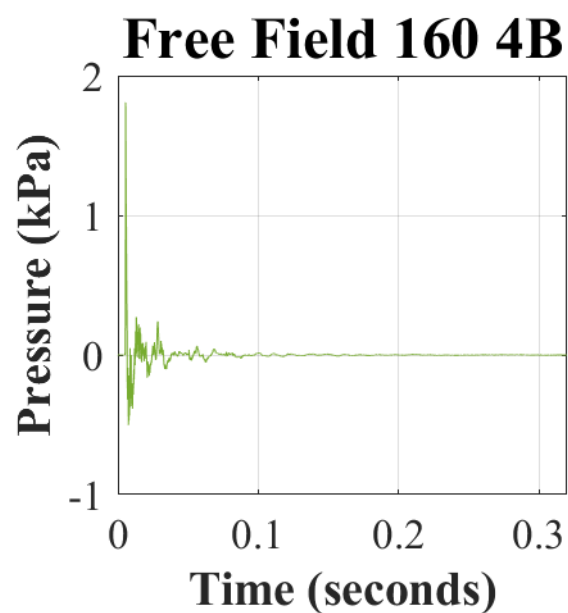
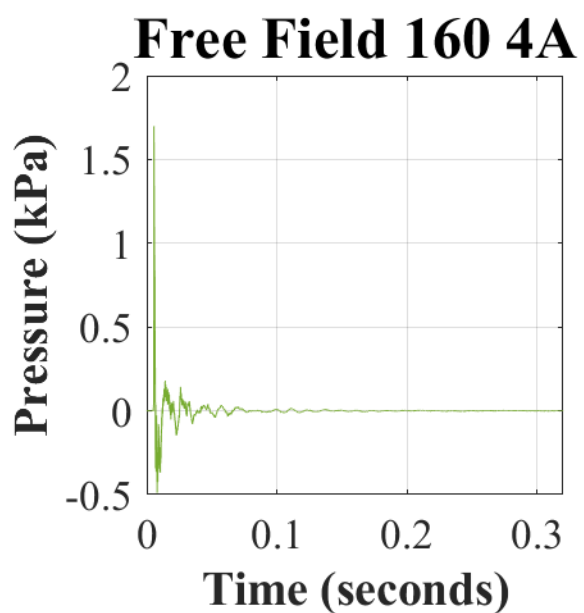
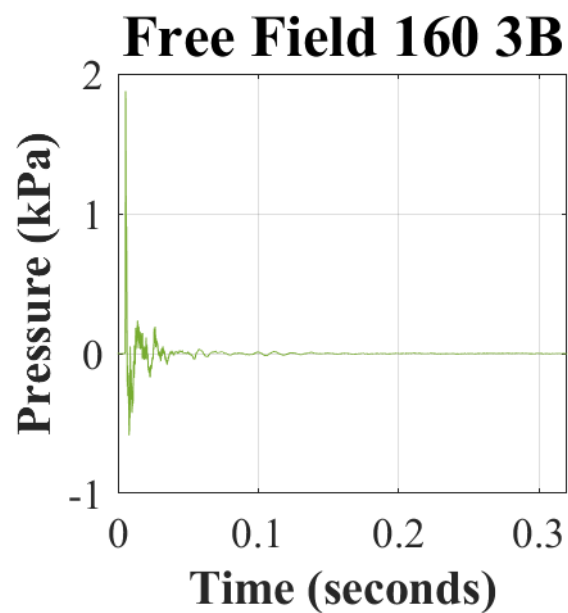
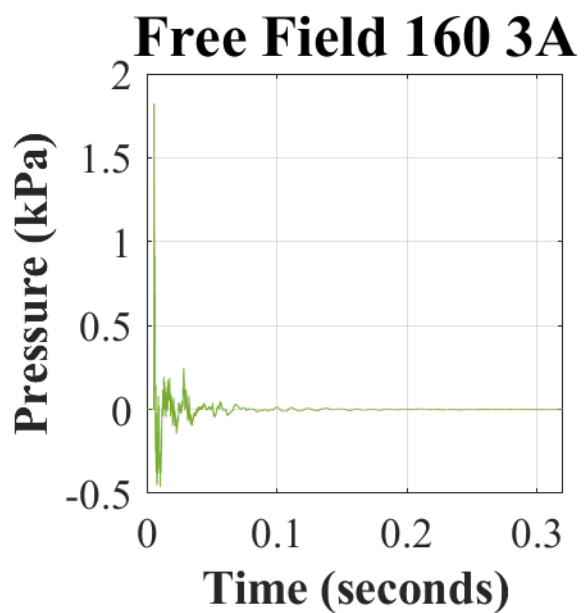


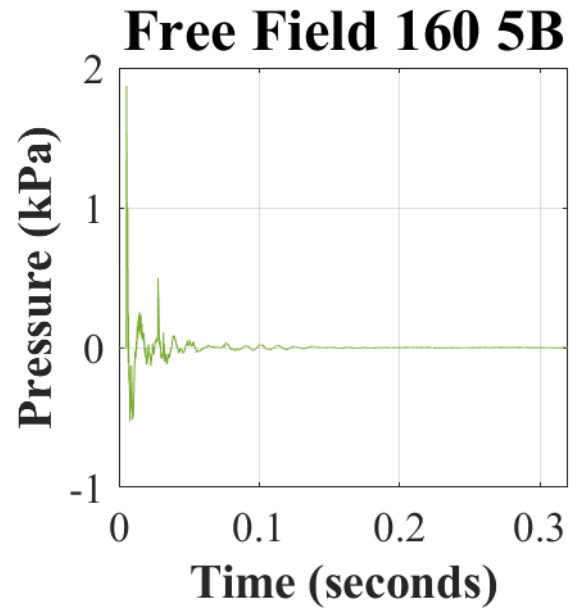
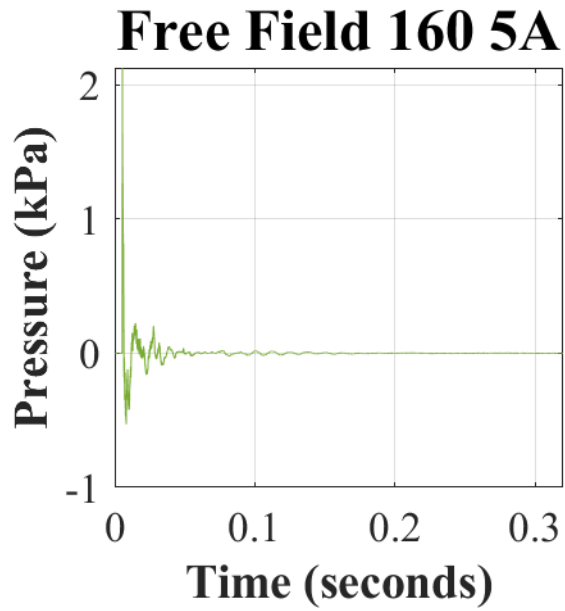


Note. The naming convention for all occluded waveforms is “Unoccluded LvL NnX”, where ‘Unoccluded’ is the test condition (i.e., ATF has the HPD doffed), ‘LvL’ is the nominal test level (i.e., 160 or 170 dBp), ‘N’ is the sample number (i.e., 1 to 5) of the device tested, ‘n’ is the trial (i.e., A or B) indicating HPD fit (i.e., first or second, respectively), and ‘X’ indicates from what ATF microphone the recording is from (i.e., right (R) or left (L) pinnae).

Appendix E. Recorded waveform (in kilopascals (kPa)) over time (in seconds (s)) of the impulse measured with the free-field probe at 160 dBp and the Pura-Fit[®] Uncorded Earplugs donned.

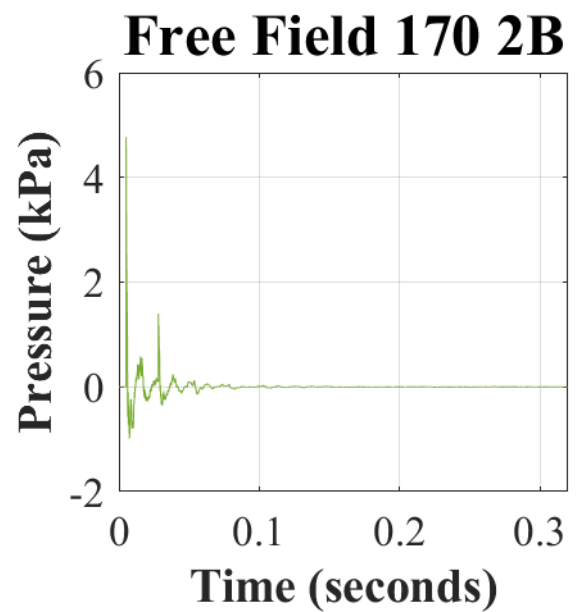
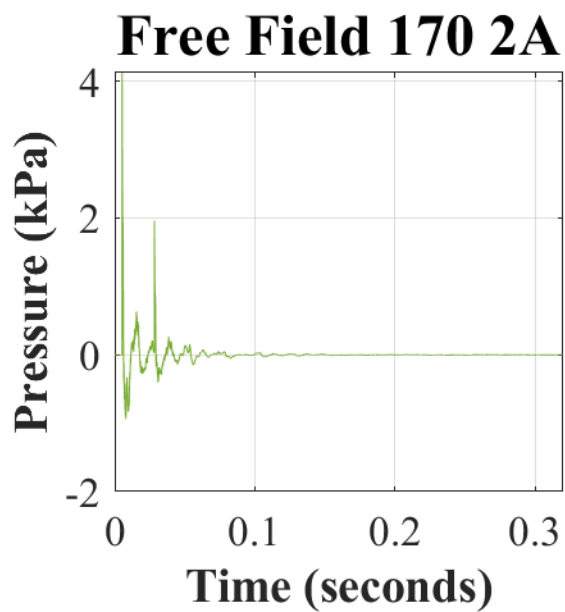
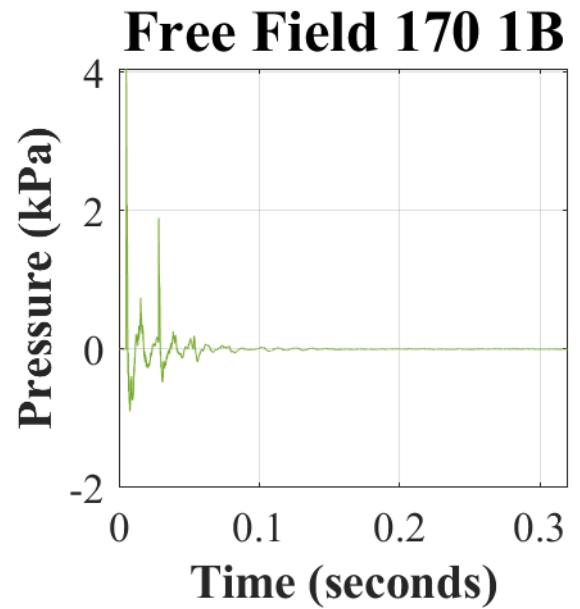
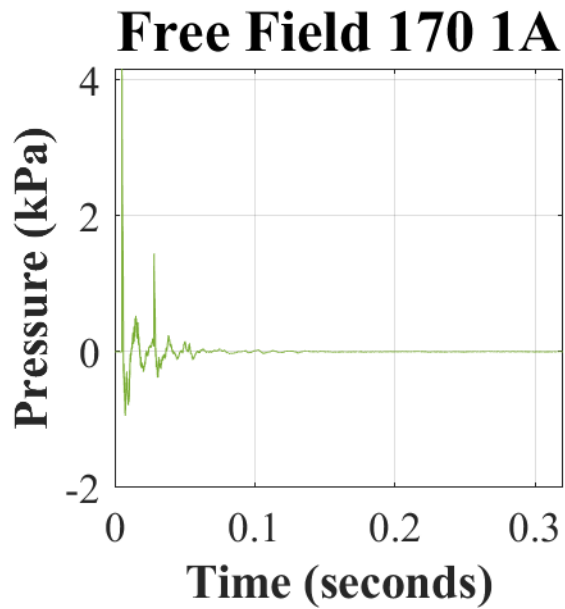


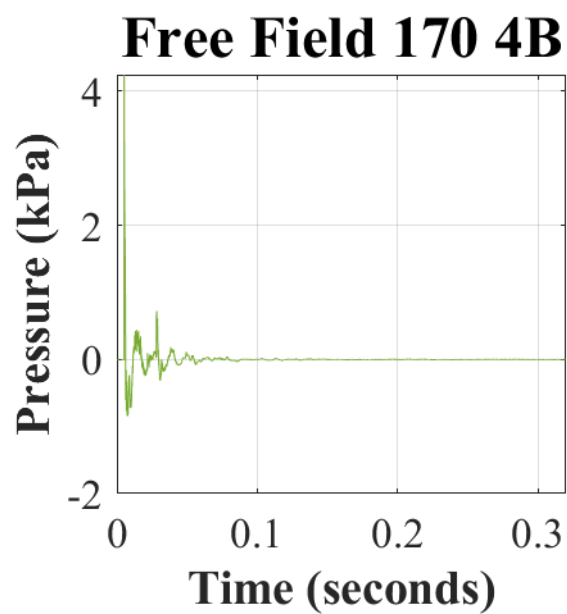
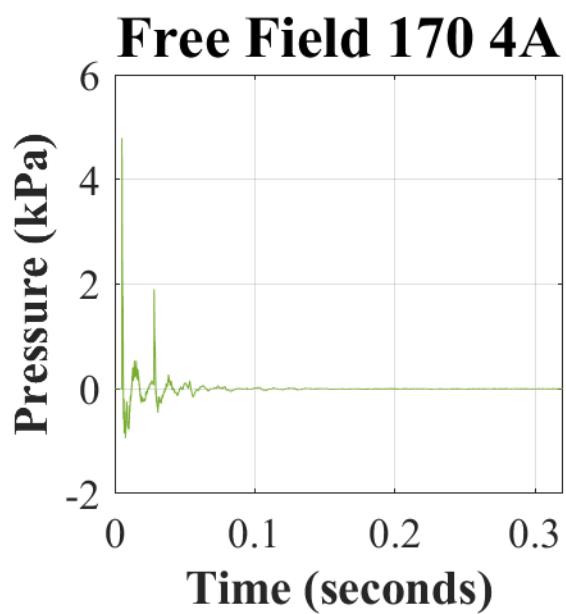
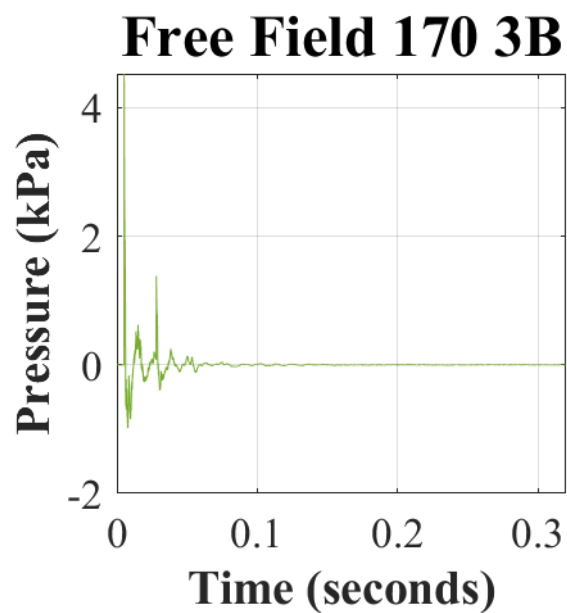
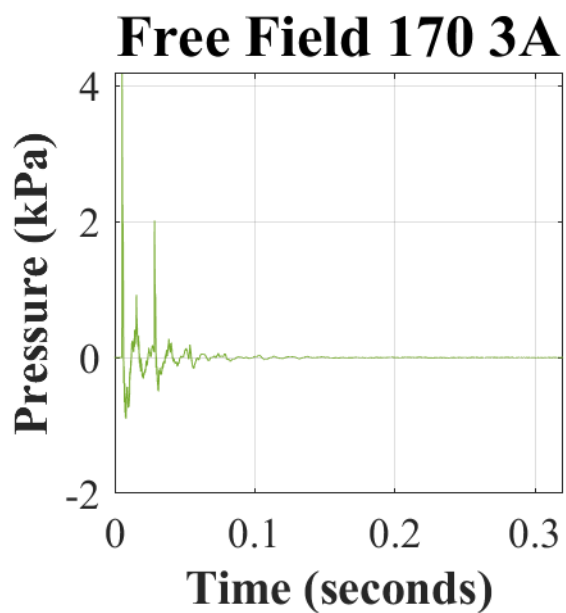


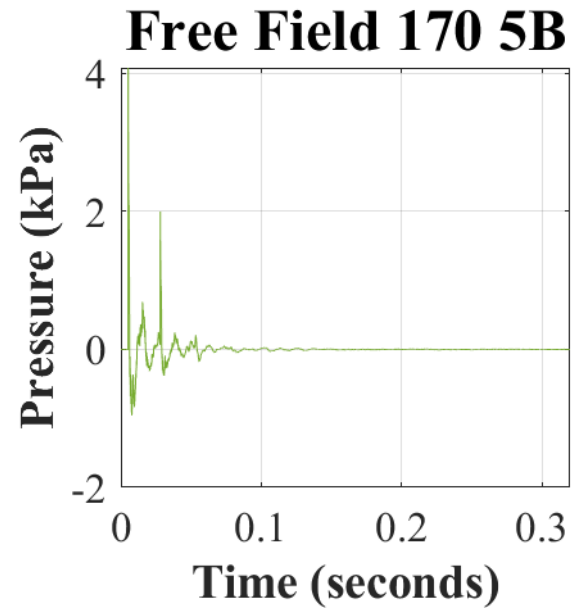
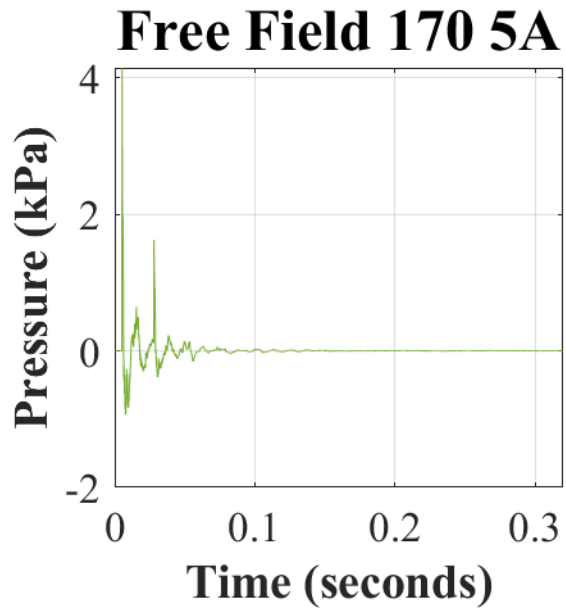


Note. The naming convention for all free-field waveforms is “Free Field LvL Nn”, where ‘Free Field’ indicates that the recording was obtained using the PCB reference microphone, ‘LvL’ is the nominal test level (170 dBP), ‘N’ is the device sample number (1 to 5), and ‘n’ is the device trial (i.e., A or B).

Appendix F. Recorded waveform (in kilopascals (kPa)) over time (in seconds (s)) of the impulse measured with the free-field probe at 170 dBp and the Pura-Fit[®] Uncorded Earplugs donned.







Note. The naming convention for all free-field waveforms is “Free Field LvL Nn”, where ‘Free Field’ indicates that the recording was obtained using the PCB reference microphone, ‘LvL’ is the nominal test level (170 dBp), ‘N’ is the device sample number (1 to 5), and ‘n’ is the device trial (i.e., A or B).